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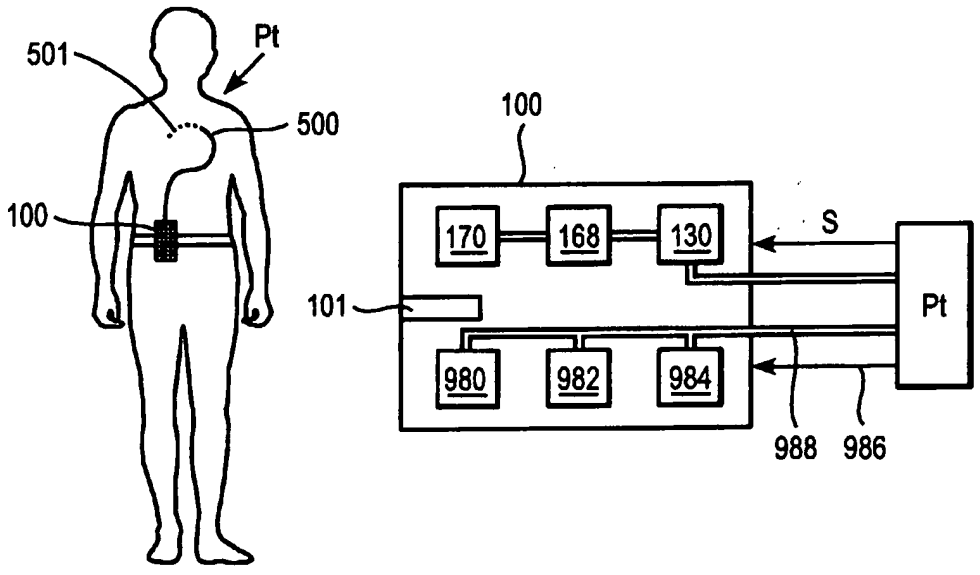

(57) Abstract: Modes, methods, systems and devices are described for providing assisted ventilation to a patient, including wearable ventilation systems with integral gas supplies, special gas supply features, ventilation catheters and access devices, and breath sensing techniques.

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METHODS AND DEVICES FOR MINIMALLY INVASIVE RESPIRATORY SUPPORT

PRIORITY CLAIM

This application claims priority to provisional application serial number 60/835,066, entitled "Methods and Devices for Minimally Invasive Respiratory Support," filed August 3, 2006, the disclosure of which is incorporated herein by reference in its entirety.

The disclosure of U.S. patent application Serial Number 10/870,849, entitled "Methods, Systems and Devices for Improving Ventilation in a Lung Area", filed June 17, 2004 and PCT patent application PCT/DE2004/001646, entitled "Method and Arrangement for Respiratory Support for a Patient Airway Prosthesis and Catheter ", filed July 23, 2004 are incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

This invention relates to ventilation therapy and oxygen therapy for persons suffering from respiratory impairment, such as chronic obstructive pulmonary disease (COPD), pulmonary fibrosis, and acute respiratory distress syndrome (ARDS).

BACKGROUND OF THE INVENTION

The following documents may be considered related art:

Patent Application PCT/DE2004/001646, Freitag, L; Method and arrangement for respiratory support for a patient airway prosthesis and catheter

US Patent Application 20050005936, Wondka; Methods, systems and devices for improving ventilation in a lung area

US Patent 5,419,314, Christopher; Method and apparatus for weaning ventilator-dependent patients

US Patent Application 20050247308, Frye, Mark R.; High efficiency liquid oxygen system

US Patent 4,938,212, Snook; Inspiration oxygen saver

Transtracheal Open Ventilation in Acute Respiratory Failure Secondary to Severe Chronic Obstructive Pulmonary Disease Exacerbation *American Journal of Respiratory and Critical Care Medicine* Vol 173. pp. 877-881, (2006),Cesare Gregoretti

Preliminary observations of transtracheal augmented ventilation for chronic severe respiratory disease. *Respir Care*. 2001 Jan;46(1):15-25., ,Christopher KL

Reduced inspiratory muscle endurance following successful weaning from prolonged mechanical ventilation.Chest. 2005 Aug;128(2):553-9 *Chest*. 2005 Aug;128(2):481-3. Chang AT

A comparison in a lung model of low- and high-flow regulators for transtracheal jet ventilation. *Anesthesiology*. 1992 Jul;77(1):189-99. Gaughan SD, Benumof JL

Tracheal perforation. A complication associated with transtracheal oxygen therapy. Menon AS - *Chest* - 01-AUG-1993; 104(2): 636-7

Dangerous complication of transtracheal oxygen therapy with the SCOOP(R) system. Rothe TB - *Pneumologie* - 01-OCT-1996; 50(10): 700-2

Patients suffering from respiratory impairment are under-oxygenated due to deteriorating lung structure and are fatigued due to the strenuous work required to get air in and out of their compromised lungs. This work leads to patients becoming dormant to reduce their oxygen consumption to reduce their work of breathing (WOB) and in turn this dormancy leads to other health problems. Long term oxygen therapy (LTOT) is a gold standard therapy widely used for decades to assist patients suffering from respiratory impairment. Typically patients are provided 1-6LPM of continuous oxygen flow into the nose via an oxygen nasal cannula. The supplemental oxygen increases the concentration of oxygen in the lung and alveolii therefore increasing the oxygen delivered to the body thus compensating for the patient's poor lung function. Improvements to LTOT have been more recently introduced such as transtracheal oxygen therapy (TTOT) and demand oxygen delivery (DOD). TTOT (US patent 5,419,314) is a potential improvement over LTOT in that the oxygen is delivered directly to the trachea thus closer to the lung and thus the oxygen is not wasted in the upper airway and nasal cavity. DOD systems (US patent 4,938,212) have been devised to sense when the patient is inspiring and deliver oxygen only during inspiration in

order to conserve the source of oxygen, a concern in the home care or ambulatory setting although not a concern in the hospital setting where the oxygen source is plentiful. LTOT, TTOT and DOD are useful in improving diffusion of oxygen into the tissues by increasing the oxygen level in the lung and bloodstream, but these therapies all have the drawback of not providing any real ventilatory support for the patient and the excessive WOB is not relieved, especially during the types of simple exertion which occur during normal daily activities, like walking or climbing stairs.

Continuous Positive Airway Pressure (CPAP) ventilation has been used extensively to provide ventilatory support for patients when LTOT alone is insufficient to compensate for a patient's respiratory impairment. However, CPAP is non-portable and is obtrusive to patients because of the nasal mask that must be worn. Further, CPAP can inadvertently train the respiratory muscles to become lazy since the neuromuscular system gets acclimated to the artificial respiratory support, a syndrome known within the respiratory medical community.

Transtracheal High Frequency Jet Ventilation (TTHFJV) as described by Benumof has also been used, for example for emergency ventilation, typically using a small gauge catheter introduced into the trachea. Frequencies are typically 60 cycles per minute or greater, driving pressures are typically around 40 psi, and flow rates are typically greater than 10LMP therefore requiring a blended oxygen air mixture and heated humidification. TTHFJV is not a portable therapy and is not appropriate as a ventilation assist therapy for an ambulatory, spontaneously breathing, alert, non-critical patient.

Transtracheal Open Ventilation (TOV) as described by Gregoretti has been used as an alternative to mechanical ventilation which uses an endotracheal tube. The purpose of TOV is to reduce the negative side effects of invasive ventilation such as ventilator associated pneumonia. Typically a 4mm catheter is inserted into a tracheostomy tube already in the patient and the other end of the catheter is attached to a conventional mechanical ventilator which is set in assisted pressure control mode and mechanical breaths are delivered into the trachea synchronized with the patients breath rate. However because the ventilator delivers a predetermined mechanical breath set by

the user the ventilator is breathing for the patient and is not truly assisting the patient. TOV is non-portable and is designed to provide a high level or complete support of a patients respiration.

Transtracheal Augmented Ventilation (TAV) as described by Christopher is a therapy in which high flow rates typically greater than 10LPM of a humidified oxygen/air blend are delivered continuously into the trachea or can be delivered intermittently or synchronized with the patients' breathing pattern. TAV is a good therapy to provide ventilatory support for patients with severe respiratory insufficiency, however TAV is not suitable for an ambulatory portable therapy because of the high flow and humidification requirement.

Current oxygen delivery therapies or ventilation therapies are either too obtrusive, or are not sufficiently compact or mobile, or are limited in their efficacy and are therefore not useful for the vast population of patients with respiratory insufficiency that want to be ambulatory and active while receiving respiratory support. Specifically a therapy does not exist which both (1) oxygen delivery to increase oxygen diffusion into the blood stream, and (2) ventilation support to relieve the WOB in a mobile device. The invention disclosed herein provides unique and novel solutions to this problem by providing an unobtrusive, ultra compact and mobile, clinically effective system that provides both oxygen diffusion support and ventilation support to address respiratory insufficiency.

SUMMARY OF THE INVENTION:

The invention described herein includes s a method and devices wherein both oxygen delivery and ventilatory support are provided by percutaneous, transtracheal, inspiratory-synchronized jet-augmented ventilation (TIJV). The therapy is provided by an ultra compact wearable ventilator and a small gauge indwelling delivery catheter.

Additional features, advantages, and embodiments of the invention may be set forth or apparent from consideration of the following detailed description, drawings, and claims. Moreover, it is to be understood that both the foregoing summary of the

invention and the following detailed description are exemplary and intended to provide further explanation without limiting the scope of the invention as claimed.

BRIEF DESCRIPTION OF THE FIGURES:

The accompanying drawings, which are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate preferred embodiments of the invention and together with the detail description serve to explain the principles of the invention. In the drawings:

Figure 1 describes graphically the difference between the present invention and the prior art.

Figure 2 describes comparing two sensors for compensating for drift and artifacts and differentiating the comparison to correlate the signal to the breathing curve.

Figure 3 graphically describes conventional oxygen therapy

Figure 4 graphically describes alternative ventilation delivery timing profiles for the present invention.

Figure 5 describes a special liquid oxygen system for delivering the ventilation therapy of the present invention.

Figure 6 describes a special liquid oxygen system with multiple outputs for delivering the ventilation therapy of the present invention.

Figure 7 describes a special compressed oxygen regulator for delivering the ventilation therapy of the present invention.

Figure 8 describes a special high output oxygen generating system for delivering the ventilation therapy of the present invention.

Figure 9 describes converting conventional oxygen supplies into a ventilator for delivering the ventilation therapy of the present invention.

Figure 10 describes a piston and cylinder for amplifying the volume output of the present invention and for achieving a higher mean output pressure.

Figure 11 describes combining oxygen insuflation of the bronchial tree with the ventilation therapy of the present invention.

Figure 12 describes the Venturi effect of the present invention.

Figure 13 describes adjusting the amplitude of the Venturi effect by catheter mechanisms.

Figure 14 describes oxygen-air blending techniques to deliver different oxygen concentrations to the patient.

Figure 15 describes use of a pressure amplifier to boost the pressure output of the oxygen source or ventilator.

Figure 16 describes a dual chamber system which alternates chambers for delivering gas to the patient.

Figure 17 describes conventional volume and timing control systems and a special timing and volume control system for delivering the ventilation therapy of the present invention in a small and low-electrically powered unit.

Figure 18 describes a piston system with a spring assisted gas delivery stroke.

Figure 19 describes a piston for the present invention with an adjustable volume output.

Figure 20 describes graphically the effect of an augmentation waveform adjustment of the present invention.

Figure 21 describes exhalation counterflow therapy to reduce collapse of the airways during exhalation, to be used in conjunction with the augmentation therapy of present invention.

Figure 22 describes tracheal gas evacuation to reduce the CO2 content in the airways, to be used in conjunction with the augmentation therapy of the present invention.

Figure 23 describes non-cylindrically shaped oxygen gas cylinders or accumulators for use in the present invention.

Figure 24 describes a 360 degree curved ventilation catheter tip to position gas delivery orifice in the center of the tracheal lumen.

Figure 25 describes a 540 degree curved ventilation catheter tip to position the gas delivery tip in the center of the tracheal lumen.

Figure 26 describes a thin wall outer cannula, stomal sleeve and inner cannula which is the ventilation catheter.

Figure 27 describes a ventilation catheter with a bend shape to position the catheter against the anterior tracheal wall and the tip orifice at a distance from the anterior wall.

Figure 28 describes a soft ventilation catheter with a stiffening or shaping member inside the catheter.

Figure 29 describes a ventilation catheter adaptable to a standard respiratory connector.

Figure 30 describes a ventilation catheter and a catheter guide, where the catheter has a non-obstructing positioning member.

Figure 31 describes a ventilation catheter with a spacer positioned to locate the catheter tip at a controlled desired distance from the anterior tracheal wall.

Figure 32 describes a ventilation catheter with a generally right angle curve to position the tip of the catheter in the center of the tracheal lumen.

Figure 33 describes a ventilation catheter with a compressible stomal tract seal.

Figure 34 describes a smart ventilation catheter with electronic tags to handshake with the ventilator.

Figure 35 describes an ostomy or stomal tract guide with deployable inner retaining flanges.

Figure 36 describes a ventilation catheter with two breath sensor arrays which use both negative and positive coefficient thermistors, useful in distinguishing between inspiration and exhalation in a variety of temperature conditions.

Figure 37 describes a screening and tolerance test algorithm and method for the purpose of evaluating a patient for the therapy of the subject invention.

Figure 38 describes a special catheter with a stepped or tapered dilation section.

Figure 39 describes the overall invention.

Reference Numerals

Q: Flow rate in LPM
t: time in seconds
y: y-axis
x: x-axis
I: Inspiratory phase
E: Expiratory phase
V: Volume
Pt: Patient
S: sensor signal
P: lung or airway pressure
T: Trachea
L: Tracheal Lumen
W: Tracheal Wall
C: Carina
LL: Left Lung
RL: Right Lung
AW: Anterior Tracheal Wall
PW: Posterior Tracheal Wall
PTCr: positive temperature coefficient reference thermistor
PTC: positive temperature coefficient thermistor
NTCr: negative temperature coefficient reference thermistor
NTC: negative temperature coefficient thermistor
R: resistor
Prox: Proximal
Dist: Distal
LPM: liters per minute
L: liters
m/s: meters per second
cwp: centimeters of water pressure
cmH2O: centimeters of water pressure
cl: centerline
1: HFJV flow curve
2: Patient breathing flow curve

500: catheter
501: Breath sensor
502: catheter ventilation gas exit port
504: catheter insuflation gas exit port
506: gas exit nozzle
510: Nozzle restrictor element
512: Nozzle restrictor element in low Jet position
514: Nozzle restrictor element in high Jet position
520: Nozzle restrictor slide
522: Nozzle restrictor slide in low Jet position
524: Nozzle restrictor slide in high Jet position
530: Reservoir inlet check valve
540: Pressure amplifier inlet stage
542: Pressure amplifier inlet gas drive pressure
544: Pressure amplifier outlet stage
546: Pressure amplifier outlet pressure
548: Pressure amplifier gas supply
550: Pressure amplifier filter
552: Pressure amplifier gas supply regulator
554: Pressure amplifier gas drive inlet
556: Pressure amplifier gas supply inlet
558: Pressure amplifier gas supply outlet
570: Accumulator A1
572: Accumulator A2
574: Accumulator A1 outlet valve
576: Accumulator A2 outlet valve
590: Volume Control valve gas inlet
591: Volume Control valve variable orifice
592: Volume Control valve body
593: Volume Control Valve needle
594: Volume Control valve outlet
596: Volume Control valve outlet pressure sensor

10: High flow O2 therapy flow curve
14: Long term oxygen therapy (LTOT)continuous flow
15: Long term transtracheal oxygen therapy continuous flow curve
16: LTOT pulse demand oxygen delivery (DOD) flow curve
18: Mechanical Ventilator flow curve
20: Patient spontaneous breath effort flow curve
24: Continuous Positive Airway Pressure (CPAP) flow curve
21: Transtracheal inspiratory augmentation ventilation (TIJV) flow curve
25: Transtracheal inspiratory augmentation ventilation lung pressure curve
30: Primary Breath sensor
32: Dampened breath sensor
34: Signal difference between primary breath sensor and dampened breath sensor
36: Prior art pressure or flow sensor signal.
38: Drift in 36
40: Artifact in 36
42: First order differential of 34
43: Patient volume curve
44: LTOT volume curve
46: LTOT DOD volume curve
50: TIJV volume curve
52: Increase in TIJV amplitude
54: Adjustment of TIJV timing to earlier
56: Adjustment of TIJV timing to later
58: Secondary TIJV volume curve
60: Secondary ventilation gas flow
100: Ventilator
101: Battery
102: Counterflow delivery valve
103: Gas evacuation delivery valve
104: Medicant delivery unit
105: Biofeedback signal
110: Liquid Oxygen (LOX) unit
112: LOX reservoir
114: Vacuum chamber
116: LOX exit tube
120: Heater
122: Check valve
124: Heat Exchanger
126: Pressure regulator
127: 2nd Pressure regulator
128: Oxygen gas reservoir
129: Toggle switch
130: Outlet On/Off valve
131: Pressure regulator manifold
132: Reservoir/accumulator inlet valve
140: O2 gas cylinder output regulator with >0.1" diameter orifice
160: Oxygen concentrator unit
162: Pump
164: Pressure amplifier
166: Pressure regulator
168: Gas reservoir/accumulator
170: Gas supply
180: Cylinder
182: Piston
183: Valve ball
210: Insuflation gas flow
220: Venturi mixing valve
222: Ventilation Gas
224: Ambient Air
598: Volume Control valve adjustment signal
600: Accumulator inlet check valves
602: Accumulator A
604: Accumulator B
606: Accumulator C
608: Valve A
610: Valve B
612: Valve C
614: Manifold
616: Orifice 1
618: Orifice 2
620: Orifice 3
640: Piston Outlet Chamber
650: Moving End Cap
652: Thread system
654: Adjustment Knob and screw
656: Adjustment drive belt
658: Rotational position sensor
660: End Cap position sensor
232: Piston Augmentation stroke spring
250: Augmentation Stroke
252: Refill Stroke 662: Pneumatic adjustment line
720: Exhalation counter-flow flow curve
722: Increased exhaled flow
724: Oscillatory counter-flow curve
726: sine wave counter-flow curve
728: Short pulse counter-flow curve
730: Ascending counter-flow curve
732: Multiple pulse counter-flow curve
734: Descending counter-flow curve
760: Non-uniform velocity profile
762: Non-diffuse gas exit
764: Uniform velocity profile
766: Diffuse gas exit
780: Gas evacuation flow curve
800: Concave accumulator/reservoir
802: Accumulator cylinder array
804: Ventilator enclosure
805: Hollow bilayer casing
806: Conduit Accumulator
808: Stomal Sleeve
809: Catheter 360 degree bend
810: Catheter 540 degree bend
811: Gas exit port
820: Guiding Cannula
830: Stiffening member
840: Anterior wall spacer
842: Catheter anterior curve
843: Catheter posterior curve
844: Adjustable Flange
850: Centering/anchoring basket
860: Short Trach Tube
864: Catheter 90 degree bend
870: Stomal seal
900: external catheter section
902: internal catheter section
904: non-Jet catheter
906: Jet catheter
908: Signature tag
910: Recognition tag
920: Sleeve external flange
922: Sleeve unfolded internal flange
924: Folded internal flange
930: Flange release cord

225: Venturi inlet port
226: Venturi check valve
230: Piston check valve

952: signal output 1
954: signal output 2
960: Wheatstone bridge circuit
962: Thermistors arrangement exposed to inhaled or exhaled flow
964: Thermistors arrangement exposed and less exposed to airflow
980: Exhalation Counterflow unit
982: Gas evacuation unit
984: Medicant delivery unit
986: Biofeedback signal
988: Auxiliary Flow

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS:

Figure 1 and Tables 1 and 2 describe the ventilation therapy of the present invention in contrast to conventional therapies. In a main embodiment of the invention a ventilation method is described in which a patient's respiration is augmented by certain ventilation-oxygen delivery parameters, delivered directly into the trachea with an indwelling percutaneous transtracheal catheter coupled to a highly compact light weight portable ventilation apparatus worn or carried by the patient, subsequently referred to as Transtracheal inspiratory-synchronized jet-augmented ventilation (TIJV). Jet pulses of gas are delivered into the trachea in synchrony with the patient's inspiratory phase.

Figures 1f and 1g describe TIJV and for comparison Figures 1a-1e describe the conventional therapies. In Figure 1a, HFJV is shown, indicating the patient breathing flow curve 2 at around 20 breaths per minute. The Jet Ventilator flow curve 1 is asynchronous with the patient's breath cycle and cycling at a rate of around 60 cycles per minute. Figure 1b describes high flow oxygen therapy (HFOT). HFOT gas source flow is applied to the patient continuously as seen by the HFOT flow curve 10. Figure 1c describes Transtracheal Oxygen Therapy (TTOT) and Pulse Demand Oxygen Delivery (DOD) therapy and the respective flow curves 14 and 16. TTOT applies continuous flow 14 to the patient, typically 1-6 LPM and DOD delivers a low flow pulse oxygen flow 16 during inspiratory phase I. Figure 1d describes Transtracheal Open Ventilation (TOV) in which a mechanical breath 18 is delivered from a conventional intensive care ventilator when a patient breath effort 20 is detected. Figure 1e describes Continuous Positive Airway Pressure (CPAP) ventilation in which the lung pressure P of the patient is elevated to the CPAP pressure setting 24.

Now referring to Figure 1f and 1g, the TIJV flow curve 21 is shown to be in synchrony with the patient's inspiratory phase I and more pronounced than DOD. As can be seen by the change in lung pressure due to TIJV 25, the therapy increases the lung pressure in the patient, thus helping the patient's respiratory muscles and showing that TIJV ventilation gas is penetrating deep in the lung.

The gas is delivered at a frequency that matches the patient's breath frequency, typically 12-30 cycles per minute, thus at a relatively low frequency compared to HFJV which is typically 60 cycles per minute. A low minute volume of gas is delivered relative to CPAP, HFJV and HFOT, typically 25ml-150ml per breath, or typically 10-25% of the patient's tidal volume requirement. The gas source supply flow rate is relatively low compared to CPAP, HFJV and HFOT, typically 4-8 lpm, and the incoming pressure requirement for the ventilator is relatively low relative to CPAP, HFJV and HFOT, typically 10-30psi. The gas can typically be delivered to the patient without adding artificial humidification as opposed to CPAP, HFJV and HFOT which requires heated humidification.

The gas delivery velocity, typically 25-400 meters/second, is fast relative to LTOT and DOD which are typically around 10 meters/second. The jet effect allows for better penetration of oxygen into the lungs. The relatively fast gas exit velocity also causes a Venturi effect at the catheter gas exit point which entrains and pulls into the lung gas volume from above the catheter which is typically 5-100% of the volume delivered by the catheter. This entrained gas is naturally humidified and has a beneficial effect of adding to the mechanically delivered gas to extend the benefit of the therapy but without risking drying the lower airways and without risking inadvertent aspiration of saliva from the mouth or gastric contents from the esophagus into the airway due to the relatively low frequency compared to HFJV. In HFJV therapy, 50-75% gas volume (as a percentage of the delivered gas) is entrained from the upper airway but at 60 cycles per minute risking aspiration and compromising speech. HFJV is only useful in acute critical situations.

The gas source supply in TIJV is typically either a liquid oxygen source (LOX), a compressed oxygen source, or an oxygen generation source. The system is an ultra compact portable system, lasting typically 2-8 hours depending on the size of the gas source, to maximize the mobility of the patient. With the unique TIJV parameters therefore, the pulsed gas delivery is designed to augment the patient's bulk ventilatory gas exchange, assist the respiratory muscles in breathing but without making them lazy, as well as ~~to~~ improve oxygen delivery, thus positively effecting both ventilation and diffusion.

In DOD therapy, gas is always delivered in slow low volume pulses (< 6 LPM) into the airway typically through the nasal route, thus effecting diffusion but not ventilation. Thus the invention herein is different from DOD therapy in that the gas pulses are delivered in a faster and higher volume pulse and at 12-30 LPM volumetric flow rate compared to 1-6 LPM volumetric flow rate in DOD, and therefore provides both ventilation and diffusion improvement, rather than just diffusion improvement as in DOD.

It should be noted that conventional volume controlled or pressure controlled ICU-type ventilators have the ability to deliver assisted breaths upon sensing inspiration from the patient as described by Gregoretti in transtracheal open ventilation (TOV). However, in TOV, the ventilator delivers a full or substantially full mechanical breath to the patient and dominates the patient's breathing mechanics rather than truly assisting the patient. Although not yet described in the medical community, these ventilators could be set to deliver the same pressure or volume as in TIJV. However, these types of mechanical ventilators are designed for the patient to both receive mechanical breaths and exhale that breath volume back through the large bore breathing circuit attached to the ventilator. In TIJV, there is no exhalation by the patient out through the jet catheter to the ventilator, rather all the exhale gas exits the natural breath routes. If using a conventional ventilator which by design expects to detect exhaled gas exiting the breathing circuit, the ventilator would suspect a leak in the system since there would be no exhaled gas detected and a fault condition would be triggered and the ventilator function interrupted. Therefore, conventional ventilators can not be used to deliver TIJV therapy. In fact, there would be numerous alarms and ventilator inoperative conditions triggered if attempting to use a conventional ICU ventilator to deliver the therapeutic parameters through a small bore ventilation catheter. It is neither clear or obvious how these traditional ventilators could be modified to perform TIJV, and as such, a whole new ventilator design is required to perform TIJV. Further, due to their design, conventional ventilators are inherently heavy, non-compact and not suitable for ambulatory TIJV therapy. A key to TIJV is that its light weight and small size makes it conducive to ambulatory therapy. Ideally, a TIJV ventilator, including gas source and battery should be less than 5.5 lbs in order for it to be successfully embraced by users.

Table 1 describes the output of TIJV ventilation compared to oxygen therapy devices, indicating the fundamental differences in outputs.

Table 1: Output of Therapeutic Gas Source Systems

Source Output	TIJV	LOX		Compressed Gas		O2 Concentrato	
		Pulse	Cont.	Pulse	Cont.	Pulse	Cont
Pressure Output (dead ended, no flow, psi)	10-30	22	22	50	50	5	2
Pressure Output, open to 4' 3mm inner diameter catheter (psi)	8-15	<5	<5	10	5	3	1
Flow Output, open to 4' 3mm inner catheter (lpm)	12-30	<6	<4	1-12	1-12	4	2

Table 2 describes in more detail the output of TIJV.

Table 2: TIJV Therapy Description

Parameter	**TIJV** Transtracheal inspiratory-synchronized Jet-augmented ventilation
Indications	Ambulatory use for respiratory insufficiency
Configuration	Wear-able ventilator, fully equipped with oxygen supply and battery, with transtracheal ventilation catheter, used for open ventilation
Description	Patient's natural inspiration is mechanically augmented by a burst of oxygen rich gas
Access	Mini-trach (3-5mm) or via existing tracheostomy tube (4-10mm) or guiding cannula (4-10mm)
Volume delivered per cycle (milliliters)	25-250 5-50% of tidal volume
Peak pressure in catheter (centimeters of water pressure)	70-200
Lung pressure during delivery (centimeters of water pressure)	raised but still negative
Peak Flow (liters per minute)	12-50 LPM
Insp. Time (sec)	0.1-0.8
Rate (breaths per minute)	Patient's rate
Timing	Delivered at most comfortable point during patient's spontaneous breath, such as during peak inspiratory flow, or after muscles have reached maximum work, or early in inspiration
Synchronization	Patient decides breath pattern
Breath Sensing	Yes. Senses spontaneous airflow stream directly in airway
Gas exit Velocity (meters per second)/ Entrainment (%)	25-250 / 5-100
Humidification	Not required

In the main embodiment of the present invention, the breathing pattern is sensed for the purpose of timing and controlling the delivery of the TIJV augmentation volume delivery pulse. Figure 2 describes an embodiment of using breath sensors which compensate for drift and artifacts. Various sections of the breathing curve are distinguished by analyzing the information from the breath sensors. For example, by taking the derivative of the breathing curve, different sections of the breathing curve can be discerned. For example, the change in sign would indicate the point in inspiration when the inspired flow stops increasing and starts decreasing. Or, different points between the start of inspiration and the end of inspiration could be discerned. These different characteristic points can then be used to trigger and time the delivery of the augmentation pulse.

Figure 2a describes the patient breath flow curve 2, and a primary breath sensor signal 30 which lags the patient breath flow curve, and a dampened breath sensor signal 32 which lags the primary sensor signal. In Figure 2b, the signal delta 34 between the primary and dampened sensor signals is plotted. The delta curve 34 therefore compensates for drift 38 or artifacts 34 that can be present in a typical breath sensing systems as shown in the prior art pressure or flow sensor signal 36 shown in Figure 2c which is derived from the typical pressure or flow sensors that are commonly used. Figure 2d shows the curve of the first order differential 42 of the signal delta curve 34.

In Figure 3 conventional LTOT is described again, indicating the patient volume curve 43 and the LTOT volume curve 44. Figure 4 describes again DOD showing the patient volume curve 43 and the DOD volume curve. DOD systems deliver the oxygen to the patient when the breath sensor senses inspiration has started. Other than the response time in the system, typically 100-200 msec., the oxygen is delivered as soon as the start of inspiration has been detected.

Figure 4 describes how the present invention is different from the existing systems in that the augmentation Volume pulse 50 pulse is more pronounced and can be delivered at any strategic time within the inspiratory phase I. For example, the augmentation pulse can be delivered in the later half of inspiration after the respiratory muscles have produced their work or most of their work which occurs in the initial

"increasing flow rate" section of the inspiratory curve. When persons are ventilated while the respiratory muscles are working, it is known that these persons can neuromuscularly become lazy and will, over time, let the ventilator do more and more of the inspiratory work, thus weakening the persons inspiratory muscles which is undesirable. The present invention can avoid this problem by delivering the oxygen later in the inspiratory phase when the inspiratory muscles are not working or doing less work. Or, alternatively, the augmentation pulse can be delivered early in inspiration. For example, if the patient is under exertion, inspiratory flow is steep at the beginning of inspiration and hence a very early augmentation trigger may be more comfortable, or if the patient is at rest, when the inspiratory flow curve is slow at the beginning of inspiration, a slight delay in the augmentation trigger time might be more comfortable. Further, in the present invention the start point of the augmented pulse delivery can be adjusted backwards and forwards in the inspiratory phase as desired, by manual adjustment or by automatic adjustment for example by a feedback from a respiratory parameter. The delivery time is typically .1 to .8 seconds, depending on the length of the person's inspiratory phase and I:E ratio. Further, in the main embodiment of the present invention, breath sensors are included on the catheter to directly measure inspiratory and expiratory air flow within the trachea, as opposed to all other prior art systems which if measuring the breathing curve measure air flow or air pressure in the catheter or breathing circuit lumen. Both flow directionality and flow amplitude are measured to discern both the phase of respiration and the depth of respiration throughout the entire breathing pattern. Prior art systems are only good at measuring the start of inspiration and no other portions of the breathing curve.

Also, in the present invention, multiple pulses can be delivered within inspiration, the pulse amplitude can be adjusted 52, the pulse can be moved earlier in inspiration 54 or moved later in inspiration 56. In addition a secondary lower volume augmentation pulse 58 can be delivered adjunctively to the augmentation volume pulse 50, or a secondary ventilation gas flow 60 can be delivered adjunctively to the augmentation volume pulse 50.

Further in the main embodiment of the present invention, Figures 5-19 describe unique pneumatic drive systems to provide the pressure and flow required for TIJV.

First, in Figure 5 a unique LOX system is described to provide the pressure and flow required for TIJV, including a ventilator 100, LOX unit 110, LOX 112, LOX unit vacuum chamber 114, LOX outlet tube 116, heat exchanger 124, heater 120, check valve 122, oxygen gas reservoir 128, reservoir pressure regulator 126, gas outlet on/off valve 130, outlet to patient Pt and incoming breath signal S. Typical LOX systems include a liquid phase oxygen compartment and an oxygen gas phase compartment which is continually filled by the boiling of the liquid oxygen. The phase change is catalyzed by a heat exchanger unit. These systems maintain the gas phase compartment at about 23psi by bleeding gas to atmosphere to avoid pressurization beyond 23psi. Typical medical LOX systems have been designed specifically to conserve oxygen and as such their output is relatively weak compared to the requirements of TIJV. The compact LOX systems which are designed for portability are engineered to deliver gas at very low flow rates (<3LPM) and low pressures (below 5psi). The larger less portable LOX units are engineered for greater flowoutput however are not realistically suited for active ambulatory patients because of their larger size. The typical systems are capable of delivering oxygen gas at a continuous flow rate of below 4 liters per minute at a pressure well below 23 psi since the pressure in the gas phase compartment drops within fractions of a second when the system is opened to the patient. The gas phase compartment contains typically less than 50ml of gas and the rate of gas creation by boiling is limited to below 4 liters per minute due to the design and construction of the heat exchanger which is typically less than 20 square inches surface area. Gas flow output to the patient is also limited by the size of the orifice in the outlet valve, typically less than .10" diameter, thus restricting airflow. In the present invention the heat exchanger unit 54 is designed with greater surface area, typically greater than 30 square inches, to produce gas at the rate of 6-10 liters per minute and the outlet orifice allows that flow rate output as well, typically greater than .15" diameter. A heater 56 may be added to increase the rate of production of gaseous O2. The gas volume of the gas phase compartment is typically above 80ml and can be 250 ml, which typically includes a pressure regulator 60, a reservoir 58, check valve 66, on/off valve 62 and incoming breath signal 64. This unique design provides an oxygen gas output flowrate of above 6 LPM at above 20psi continuously, thus meet the demands of the ventilation parameters required in TIJV. The unique LOX system includes a catheter and all the

requisite sensing components and timing functions described earlier in order to deliver the required volume of gas at the correct pressure and at the correct time of the breathing curve.

In Figure 6 an additional embodiment is shown comprising a, LOX system with two pressure settings. One low pressure regulator 126 with a setting of 23psi to be used when the patient requires less powerful therapy or needs to conserve the LOX, and a higher pressure regulator 127 with a setting of for example 30-50psi for increasing the output of the unit when needed or when conserving the LOX is not a concern. For example, when traveling on an airplane, the LOX system can be-set at the low 23 psi setting, and reset to the high setting after the flight or when arriving to the destination where there is a refill station. The two pressure regulators are configured in a manifold 131 which can be operated by a switch 129 to switch between settings. During flight, the patient can still receive the TIJV therapy but at a lower level of augmentation corresponding the to 23psi setting, but after the flight and when the patient becomes more active again, the augmentation level can be increased because the pressure is set to the higher output setting. Two pressure settings are exemplary and it can be any number of pressure settings or even a continuous adjustment of the pressure setting between a minimum and maximum value.

Figure 7 describes an alternate embodiment in which a compressed oxygen gas source is combined with the TIJV ventilator features to create an integrated ventilator and gas source unit. The output regulator of the oxygen cylinder has a larger orifice than in a traditional oxygen therapy gas flow regulator, typically 0.1-0.2 inches in diameter, such that the flow output can be boosted to > 6 LPM and meet the demands of TIJV.

In Figure 8 an alternate embodiment to the present invention is shown comprising a unique oxygen generating device which can be used to provide the requisite ventilation parameters. An oxygen generator unit 160 is integrated into a ventilator 100 which includes a pump 162, a pressure amplifier 164, a gas reservoir/accumulator 168, a reservoir inlet regulator 166, and a reservoir outlet on/off valve 130. Typical oxygen generating devices produce a relatively weak output of

oxygen (<2LPM at < 5psi). By increasing the storage capacity and optionally including a pneumatic pressure amplifier, the output can be boosted to 4-10LPM and 10-30psi., thus powerful enough to meet the pressure and volume needs of TIJV. This unique oxygen generator system includes a catheter and all the requisite sensing components and timing functions described earlier in order to deliver the required volume of gas at the correct pressure and at the correct time of the breathing curve as required with TIJV therapy.

Figure 9: In another main embodiment of the present invention, TIJV therapy can be accomplished by using a conventional gas source 170, such as a LOX systems, compressed gas tanks, or oxygen generator systems, but with a unique volume accumulator 168 and inlet valve 132 placed in between the gas source and the patient. The accumulator acts as a capacitor and stores a pressurized volume of gas close to the patient. The outlet of the accumulator is relatively unrestricted so that a relatively high flow rate can be delivered to the patient during the augmentation time and therefore meeting the requisite volume and pressure requirements. During the augmentation delivery period, the accumulator is depressurized to the patient through a valve which is switched open and during the non-augmentation time the accumulator is re-pressurized from the gas source by closing the patient valve and opening a valve between the accumulator and the gas source. Because the augmentation:non-augmentation time ratio is typically 1:2 – 1:3, the accumulator is able to be sufficiently re-pressurized in between augmentation pulses. Without the accumulator, the conventional gas supply systems do not have enough flow rate output and/or pressure output to meet the ventilation parameters of TIJV. A further benefit to this embodiement is safety; because of the valve configurations, if a valve where to fail open, only the cylinder volume could be delivered to the patient. This unique accumulator system is accompanied by all the requisite sensing components and timing functions described earlier in order to deliver the required volume of gas at the correct pressure and at the correct time of the breathing curve.

Figure 10: In another main embodiment of the present invention, TIJV therapy can be accomplished by using conventional gas sources (LOX systems, compressed gas or O2 concentrators), but with a unique cylinder and piston placed in between the gas

source and the patient. Flow from the gas source 170 flows through an inlet valve 132 into a cylinder 180, moving a piston 182 while an outlet valve 130 is open to the patient Pt and closed to the gas source 170. A valve ball 183 or similar valve feature prevents the gas source from being directly connected to the patient. The cylinder stores a pressurized volume of gas similar to the accumulator system described previously in order to boost the flow rate to the patient to meet the TIJV requirements. In addition however the piston in the cylinder compresses the volume in the cylinder as the gas is being delivered to the patient, therefore reducing the pressure and flow rate decay occurring in the cylinder (due to the compression) and therefore boosting the volume delivered to the patient in a given period of time and maintaining peak pressure of the delivered gas for a longer period of time. A further benefit to this embodiment is safety; because of the valve configurations, if a valve where to fail open, only the cylinder volume could be delivered to the patient. This unique accumulator/piston system is accompanied by all the requisite sensing components and timing functions described earlier in order to deliver the required volume of gas at the correct pressure and at the correct time of the breathing curve. Comparison of Figures 10b which represents a cylinder 180 with no piston and Figure 10c which represents a cylinder 180 with a piston 182, shows the increase in mean pressure output and volume caused by using the piston.

Figure 12 describes in more detail the jet effect of the invention. A unique catheter 500 is described to deliver the gas to the patient in the appropriate manner. The delivery catheter may include a nozzle 506 or diameter restriction at its distal tip (the patient end) located above the carina C in the lumen L of the trachea T. The nozzle is dimensioned so that the exit velocity of the gas is increased creating a venturi effect in the local area around the catheter tip. The venturi entrains air from the upper airway above the catheter and pulls that entrained air 400 into the left lung LL and right lung RL with the augmentation jet flow 21. Thus, the total amount of therapeutic gas provided to the patient is the TIJV augmented volume (VA) 50 being delivered from the ventilator, plus the entrained volume (VE) 400, thus adding to the ventilatory support provided by the VA alone. Since the VE is pulled from the upper airway, it is naturally humidified and in this manner, TIJV can be successful for longer periods of time without adding artificial humidification. Further, the exit velocity can be designed

such that there is for example 50% entrainment, so that only half of the therapeutic volume comes from the ventilator, thus doubling the length of use of the portable oxygen supply being used. The jet can be tailored to provide 5%-100% entrainment, and if desired can even cause >100% entrainment. For comparison, the effects of TIJV are compared to DOD indicating TIJV increases entrained volume and reduces patient respiratory rate because the patient's breathing becomes less strenuous, whereas DOD does not effect these parameters.

Alternatively, as shown in Figure 13 the nozzle dimensions at the tip of the catheter can be automatically and/or remotely adjustable, for example by moving an inner element or by inflating or deflating a element near the tip ID. For example a nozzle restrictor element 510 can be deflated 512 to produce a low jet output and can be inflated 514 to produce a high jet output. Or a nozzle restrictor slide 520 can be moved from less restricted nozzle position 522 to a more restricted position 524 to increase the jet effect. In this embodiment the nozzle would be adjusted to alter the percentage of entrained airflow, for example if the patient sensed dryness in the nasal cavity or sensed saliva being aspirated into the trachea, the amount of jet velocity could be reduced without removing the catheter in order to reduce the amount of entrained gas from above the catheter. Or if the patient needed more mechanical support then the jet could be increased. The jet adjustment could optionally be done automatically by use of physiological feedback signals.

Figure 14: In a further embodiment of the present invention, ambient air can be mixed in with the oxygen gas being delivered with a low or no electrical power consuming mixing device. For example, ambient air can be mixed in with the pressurized oxygen by sucking the air in by creating a venturi effect with the pressurized flowing oxygen gas, or air can be added by the appropriate valving, or can be added by check valves in a mixing chamber, or can be added to mixing chamber with a small, low-power consumption pump. For example in Figure 14a, a Venturi air mixing unit 220 is shown receiving oxygen rich gas 222 from a gas source, a venturi port 225 with check valve 226 for sucking in ambient air 224. Also for example in Figure 14b a piston system is shown comprising a piston 182 with check valves 230 such that when the piston strokes 250 to deliver volume to the patient the check valves

are closed, and when the piston performs a refill stroke, air enters the chamber through the check valves. Air 224 is brought into the cylinder 180 through an inlet valve 132 and oxygen rich ventilation gas 222 is brought into the cylinder through the outlet valve 130. Oxygen rich ventilation gas mixed with air is then released to the patient through the outlet valve. The addition of air into the oxygen gas extends the duration of use of the compact portable system. For example a system using a 1 liter cylinder of compressed oxygen can last 2 hours if the ventilator is delivering augmentation pulses of 100% oxygen, however if ambient air is mixed in so that the augmentation pulses are 50% oxygen and 50% nitrogen, then the 1 liter cylinder can last approximately 5 hours.

Figure 15: In another embodiment of the present invention a pressure amplification device is used to boost the pressure output of the system to the patient. The ventilator 100 includes a gas source 170, a pressure amplifier unit 530, a reservoir/accumulator 168, on on/off valve 130, flow to the patient Pt and an incoming breath signal S. The pressure amplifier unit includes an inlet stage 540 receiving a drive air pressure 542 and an outlet stage 544 emitting a amplified air pressure 546. Schematically the amplifier includes a gas supply 548, a filter 550, a regulator 552, a gas drive inlet 554, and a gas supply outlet 558. Incoming pressures from the gas supply can be as low as 1psi and amplified to 10-30psi., thus providing adequate pressure and flow to accomplish TIJV. Alternately, the output of the pressure amplifier can be stored in an accumulator which will boost the volume that can be delivered during depressurization of the accumulator during an augmentation pulse as described previously. The pressure amplifier will allow a relatively weak gas supply such as a small LOX system, an oxygen concentrator system, or a low powered electrical air pump to be used for the gas source. The pressure amplifier unit can be pneumatically powered or electro-pneumatically powered.

Figure 16: In another embodiment of the present invention, multiple accumulators or pistons are used to store and deliver the augmentation volume. The ventilator 100 includes a gas source 170, an array of accumulators 570 and 572, with outlet valves 574 and 576 and a main outlet valve 130 to the patient Pt. The accumulators or pistons can alternate such that for example a first accumulator or piston depressurizes to the patient for a first augmentation pulse and a second

accumulator or piston depressurizes to the patient in the next augmentation pulse. In this manner, each accumulator or piston has a longer re-pressurization time (twice as long compared to a system with one accumulator or piston), therefore able to deliver sufficient volume during the augmentation pulse because of starting to depressurize from a higher pressure. This embodiment is particularly useful in fast breath rate situations for example greater than 30 breaths per minute.

Figure 17: In another embodiment of the present invention, a unique system is described to provide independent control of augmentation volume and augmentation time for delivering TIJV, but without using a pressure or volume feedback loop. Figure 17a describes the conventional approach of a flow control valve with a needle, 593, a variable orifice 592, a valve body 591, a valve inlet 590 and outlet 594, a pressure or flow sensor 596 and a feedback adjustment signal 598. In the invention shown in Figure 17b, an array of accumulators 602, 604 and 606 with check valves 600 and an array of orifices 616, 618, and 620 of different sizes are arranged with a valving system 608, 610, and 612 and manifold 614 such that any reasonably desired augmentation time and augmentation volume can be delivered by activating the correct combination of accumulator(s) and using the correct orifice size. This embodiment allows for independent selection of augmentation volume delivery time and augmentation volume. For example, 100ml can be delivered in 0.2 seconds or can be delivered in 0.4 seconds, depending on what is desired.

Figure 18: In another embodiment of the present invention a piston with a spring is used to amplify volume delivered to the patient. The reservoir/accumulator 168 includes a cylinder 180, a moving piston 182, an outlet valve 130 to the patient PT, a pressurization and depressurization outlet chamber 640, and a spring 232. The piston strokes in one direction by the cylinder depressurizing through a valve 130 to the patient. A compressed spring 232 on the opposite side of the piston adds speed to the moving piston, thus increasing the cylinder outlet flow rate to the patient. The cylinder then re-pressurizes through the valve 130 and compresses the spring 232 and repeats the cycle for the next augmentation delivery.

Figure 19: In another embodiment of the present invention, an adjustable volume cylinder is used to modify volume delivery. In this embodiment shown, the piston in the cylinder stokes from side to side and each stroke sends volume to the patient while to opposite side of the chamber on the other side of the piston is re-pressurizing from the gas supply in preparation for the next stroke to the patient. The cylinder 180 includes a moveable piston 182, inlet and outlet valves on both ends of the cylinder 130 and 132, a moveable end cap 650, a thread system 652 used to move the end cap, an adjustment knob and screw654, optionally an adjustment drive belt 656 or other drive system, optionally a knob and screw rotational position sensor 658, and optionally an end cap axial position sensor 660. The adjustment can be manual, for example by use of the knob and screw to move one end cap of the cylinder inward or outward. The changed volume will affect the volume delivered during the cylinder depressurization because of the changed capacitance of the accumulator. Alternatively, the adjustment can be electronically controlled and optionally the adjustment position can be sensed for display or control loop function by use of sensors, 660 or 658. Also, alternatively the same adjustment mechanisms can be applied to the piston embodiments described previously.

Figure 20: In another embodiment of the present invention, the augmentation pulse can be shaped in a desired waveform. This is accomplished for example by control of the piston stroke speed which can be controlled with a variable orifice on the outlet of the cylinder, or gas source pressure or stoke speed. For example as shown in the graphs the TIJV volume 50 can be a sine wave, square wave, descending wave or ascending wave.

Figure 21: In another embodiment of the present invention exhalation counter-flow is described which will have the effect of reducing collapse of the diseased, collapsible distal airways by giving those airways a back pressure. An increase in exhaled flow 722 and more volume is then able to be exhaled by the patient during exhalation. The exhalation counter-flow can be delivered in a variety of pressure or flow profiles, such as a square exhalation counter-flow flow curve 720, a short pulse 728 , multiple pulses 732, ascending or descending profiles 730 and 734, oscillation 724, sign wav 726, or at the beginning or end of exhalation and at high, medium or low

amplitudes. The exhalation counter-flow can be delivered by the piston described previously while the piston is stroking in the opposite direction of an augmentation stroke, or it can be delivered by a simple valve between the patient and the gas supply, or by a second cylinder or piston independent of the augmentation delivery mechanism. A catheter 500 is shown in the lumen L of the trachea T. The exhalation counterflow gas exit from the catheter can be non-diffuse 762 to cause a non-uniform velocity profile 760, or can be diffuse 766 to create a more uniform velocity profile 764. The gas exit dynamics are adjusted by the gas exit ports on the catheter, a signal port is useful for non-diffuse gas exit and several small side ports are useful for diffuse gas exit. The velocity profile is selected based on the collapsibility of the patients' airways; for example a more uniform profile is used for higher degrees of collapsibility. The counterflow amplitude can also be adjusted manually or automatically based on a physiological signal such as CO2, exhaled flow, volume change.

Figure 11: In another embodiment of the present invention tracheal gas insufflation flow 210 can be delivered to create a higher oxygen gas concentration in the upper airway, adjunctively to the TIJV augmentation flow 21. The catheter 50 includes an augmentation flow exit port 502 and an insufflation flow exit port 504. The insufflation can be delivered at a strategic time during the patient's inspiratory phase or can be delivered at a strategic time during the patient's expiratory phase. For example, if insufflation is delivered during the 250msec of inspiration that precedes the augmentation pulse, then the entrained air sucked into the lung by the augmentation jet will be higher in O2 content. Or, if insufflation is delivered during exhalation it can have the effect desired plus also provide exhalation counterflow described previously. The amplitude of the insufflation flow can be adjustable, manually or automatically.

Figure 22: In another embodiment of the present invention tracheal gas evacuation is used to lower the CO2 content in the trachea, which will cause a lower CO2 content in the distal compartments of the lung due to mixing and diffusion that will occur because of the concentration gradient. The evacuation flow 780 can be applied during inspiration, exhalation or both and the evacuation profile can be constant, oscillatory, synchronized, sinusoidal, etc., or can be applied intermittently at a

rate and amplitude as determined by biofeedback such as by monitoring CO2 levels in the trachea.

Figure 23: In another embodiment of the present invention, the ventilator can include a non-cylindrical gas accumulators or gas supply reservoir in order to optimize the overall shape of the compact ventilator, since an optimally small ventilator may not accommodate the conventional shape of a gas cylinder. For example the shape can be concave 800, or an interconnected series of cylinders 802, or a conduit system 806. Or the ventilator enclosure 804 itself can comprise the gas reservoir or gas supply by having a bilayer casing 805. In the case shown the ventilator enclosure cross section is bone-shaped, however it could be of any reasonable shape. Unorthodox shaped reservoirs are capable of handling the typical working pressure of the invention which is below 50psi.

In another embodiment of the present invention, the ventilator is electrically powered by a manual hand-cranked charging generator unit, either internal to the ventilator or externally connected to the ventilator, (not shown).

In another embodiment of the present invention the ventilator can receive gas flow and pressure by a manual pneumatic pump system actuated by the user, (not shown).

In other embodiments of the present invention shown in Figures 24-33, catheter designs are described which will space the catheter tip in the center of the trachea, so that the tip is not poking, irritating or traumatizing the wall of the trachea, a problem described with other transtracheal catheters. Also, stabilizing the catheter tip in the center of the tracheal lumen so that the tip does not whip during the jet pulse is important. Whipping, a problem with other catheters, can cause tracheal wall trauma. Further, the tip should be directed generally in the direction of the carina C and not towards a tracheal wall W, in order for the augmentation pulse to effectively reach the lower portions of the left lung LL and right lung RL.

Figure 24: In one embodiment of the invention, a looped catheter with approximately a 360 degree curve 809, is described which is inserted through a stomal

sleeve 808 and contacts the anterior wall AW, spaces it from the posterior wall PW, and spaces the catheter gas exit port 811 in the center of the tracheal lumen L. The catheter lumen beyond the exit port is occluded so the gas can exit out of a the port 811, or the loop can extend so that the catheter tip points downward toward the carina. The catheter loop is biased so that the anterior section of the loop is always touching the anterior tracheal wall thus assuring that the catheter exit port will be somewhere in the middle of the tracheal lumen. Alternatively as shown in Figure 25, the catheter can comprise approximately a 450-540 degree loop 810 so that the distal tip is directed down toward the carina. In this embodiment it may be more advantageous for the catheter bend to be biased such that there is contract with either or both of the anterior and posterior tracheal wall. This embodiment will also apply a gentle tension on the tracheal wall to help keep it in position, however when the trachea collapses with coughing, the curved catheter will compress with the trachea.

Figure 26: In another embodiment of the invention a dual cannula design is described with an ostomy or stomal sleeve 808. The outer guiding cannula 820 removably attaches to the sleeve so that the guiding cannula can be removed and reinserted conveniently. The guiding cannula is especially thin wall, for example 0.010" – 0.030" and is typically made of a braid or coil reinforced elastomer or thermoplastic to resist kinking. The guiding cannula, although semi-rigid, is short compared to the front-to-back width of the trachea and therefore is atraumatic. The inner cannula is the TIJV catheter and is dimensioned to fit the ID of the guiding cannula snuggly. The tip of the TIJV catheter extends beyond the tip of the guiding cannula. The guiding cannula semi-rigidity provides a predetermined known track for the TIJV catheter to follow and therefore positions the TIJV catheter tip somewhere in the tracheal lumen and not touching the tracheal wall.

Figure 27: In another embodiment of the invention a shaped catheter design is described which is intended to remain close to the anterior wall of the trachea, thus when the patient's trachea collapses during coughing or bronchospasm, the posterior wall is not irritated. Near the tip of the catheter the catheter makes a gentle anterior bend 842 and posterior bend 843 such that the tip is directed away from the tracheal anterior wall. The stomal sleeve inner flange 922 provides a spacing of the catheter

away from the anterior wall in that location. The catheter includes an flange 844 that can be adjustable. Alternatively the catheter tip can include an atraumatic spacer that pushes it away from the anterior tracheal wall.

Figure 28: In another embodiment of the invention a catheter design is described which is comprised of extremely soft material, for example 30-60 shore A so that it does not irritate the tracheal wall when it comes in contact with it. The shape of the soft highly flexible catheter is maintained by a rigid filament stiffening member 830 imbedded into the catheter construction, for example a thin stainless steel, thermoplastic or shape memory wire shaped-set into the required and desired shape.

Figure 29: In another embodiment a catheter is described which is connected to the male connector of a standard tracheal tube such as a short tracheostomy tube 860 or a laryngectomy tube and which includes a protruding or extending sensor 900 which extends through the length of the tracheal tube and into the tracheal airway where the sensor can sense airflow.

Figure 30: In another embodiment of the invention a catheter design is described that has an anchoring basket 850 to center the catheter in the tracheal lumen. The basket is highly forgiving such that partial or full collapse of the tracheal diameter (during coughing or spasms) is not impeded by the basket and any contract is atraumatic. The basket material must be lubricious and rounded so that it does not encourage granulation tissue growth and become attached to the tracheal wall. The basket is typically releasable from a sleeve for easy insertion and removal but can also be easily inserted and removed through the ostomy due to its compliant nature. Alternatively, the basket can be an inflatable fenestrated cuff.

Figure 31: In another embodiment of the invention a catheter design is described which includes a spacer 840 that spaces it from the anterior wall of the trachea. The spacer can be a soft material or a shape memory foam encapsulated in a highly compliant membrane. Or, the spacer can be an inflatable cuff. The cuff can be a normally deflated cuff that requires inflation by the user, or can be a normally inflated and self inflating cuff which requires deflation for insertion and removal. The spacer can be a protrusion of the stomal sleeve 808 or the catheter 50.

Figure 32: In another embodiment of the invention a shaped catheter design is described which is intended to distend in the tracheal lumen minimally, by being shaped in a right angle or approximately a right angle 864. This shape allows the tip of the catheter to be directed downward toward the carina, but with a very short catheter length. This shape may be advantageous when the trachea is moving and elongating since the body of the catheter will not be contacting the tracheal walls, unless the trachea is collapsed. The catheter also includes an adjustable flange 860 to set the required depth of insertion of the catheter.

Figure 33: In another embodiment a catheter is described comprising a compliant and/or inflatable sealing sleeve 870 for sealing and securing the catheter shaft transcutaneously to the ostomy site. The sleeve can be a self deflating or inflating or a manually deflating or inflating design, for example a memory foam encapsulated by a compliant elastomeric membrane with a deflation bleed port.

Figure 34: In another embodiment a smart catheter is described in which there is a proximal external catheter section 900 and distal internal catheter section 902 which connect to each other. Each section contains a miniature device that produces an electrical signature wherein the distal section signature tag 908 is recognized by the proximal section recognition tag 910. In this manner, different catheter designs for different therapeutic modes can be attached to the ventilator unit, and the ventilator unit will detect which catheter and therefore which mode should be used. For example, a non-jet catheter 904 can be attached and the ventilator can switch to non-jet mode, and a jet catheter 906 can be attached and the ventilator switches to a jet mode. Or the electrical signature can track usage time and alert the user when the catheter needs to be replaced or cleaned. Or the signature can be patient specific or distinguish between adults and pediatric patients, or to report on therapy compliance.

Figure 35: In another embodiment a transtracheal catheter sleeve 808 is described for placement in the trachea transcutaneous ostomy site. The sleeve comprises a proximal flange 920 and a distal flange 922 for the purpose of positioning the distal end of the sleeve just barely inside the tracheal lumen and preventing inadvertent decannulation of the sleeve. The distal flange is retractable into the main

lumen of the sleeve so that when the sleeve is being inserted into the ostomy the retracted flange 924 is not protruding and the sleeve can assume a low profile for easy and atraumatic insertion. Then, when inserted into the trachea, the flange can be deployed by pushing a trocar against the retracted flange or by releasing a release cord 930 which was keeping the flange in the retracted state.

Figure 36: A sensor arrangement is described which combines negative thermal coefficient NTC and positive thermal coefficient PTC thermistors to detect cooling and heating for the purpose of determining breath flow directionality. The NTC thermistor is especially effective in detecting inspiration; as the thermistor is cooled by the cooler inspired air, the start of inspiration is detected. The PTC thermistor is especially effective in detecting exhalation; as the thermistor is heated by the warmer exhaled air the start of exhalation is detected. An external reference thermistor is used to measure ambient temperature. If the ambient temperature is cooler than body temperature which will normally be the case, the arrangement described is used, however if ambient temperature is warmer than body temperature, then the operation of the NTC and PTC thermistors is reversed. Each thermistor is paired with a reference thermistor NTCr and PTCr and the signals from each pair of sensing thermistor and its reference thermistor are processed through an electronic comparator, such as a wheatstone bridge 960 with resistors R to complete the bridge, to yield a dampened output signal 952 and 954 that dampens artifacts in the respiratory pattern and drifts that occur because of surrounding conditions. Alternatively, the thermistor sensors can be heated by applying a voltage to them such that their resting temperature and resistance is kept at a known constant value. Therefore, heating and cooling from inspiration and exhalation is highly predicable when ambient temperature is known. For example, the thermistors can be warmed to a temperature of 120 degrees F. Exhalation cools the thermistor less than inspiration and therefore the breath phase can be determined. The thermistors can be arranged on the catheter such that the positive coefficient thermistors are located on the side of the catheter facing exhaled flow, and the negative coefficient thermistors are located on the side of the catheter facing inspired flow, 962. Or alternatively, the thermistors can be spacially arranged in some other strategic orientation such as placing the sensing thermistors such that they are fully exposed to airflow and the reference thermistors such that they less exposed to airflow 964.

In another aspect of the present invention, sensors are included to provide biofeedback for a variety of purposes. For example, the presence of coughing or wheezing or dyspnea is monitored by comparing the measured breathing curve to algorithms in the software. If an exacerbation is detected, a medicant can be delivered, such as a bronchodilator. Or, tracheal humidity can be monitored for the purpose of increasing or decreasing the delivered volume so that the lung does not become dry, or alternatively the jet venturi can be increased or decreased to increase or decrease upper airway entrainment, in order to maintain the correct lung humidity or correct ventilation volume. Or, patient activity level can be monitored with an actigraphy sensor and the ventilation parameters can be adjusted accordingly to match the activity level of the patient. Or the patient's venous oxygen saturation can be measured in the percutaneous ostomy by a pulse oxymetry sensor placed in the ostomy sleeve or in the catheter and the ventilation parameters adjusted accordingly. Or the patient's tracheal CO2 level can be measured with a CO2 sensor and the ventilation parameters adjusted accordingly. All these prospective measured parameters can be transmitted by telemetry or by internet to a clinician for external remote monitoring of the patient's status.

Figure 37: Another potential problem of new minimally invasive ventilation and oxygen therapy modalities is the patient acceptance and tolerance to the new therapy, and the acclimation of the body to the intervention such as a minitracheotomy. For example patients may not want to have an intervention performed unless they can experience what the effect of the therapy will be. Or for example, the body may be initially irritated by the intervention, and if the therapy is started immediately after the intervention, the benefit may be spoiled by other physiological reactions. Therefore in another aspect of the present invention a novel medical procedural sequence is described, to allow the patient to experience the therapy and to acclimate the patient to the intervention before the therapy is started. The patient is subjected to a tolerance test by using a non-invasive patient interface such as a mask or nasal gastric tube or a laryngeal mask or oropharyngeal airway (NGT, LMA or OPA). In the case of using the NGT the patient's nasal cavity can be anesthetized to allow the patient to tolerate the NGT easily. TIJV is then applied to the patient in this manner for an acute period of time to determine how well the patient tolerates the therapy. Also, information can be

extracted from the tolerance test to extrapolate what the therapeutic ventilation parameters should be for that patient. After the tolerance test, a mini-otomy procedure is performed and an acclimation sleeve and/or acclimation catheter is introduced into the airway. After a subchronic acclimation period with the temporary sleeve/catheter, for example one week, the therapeutic catheter and/or ostomy sleeve is inserted into the patient and the therapy is commenced, or alternatively another brief acclimation period will take place before commencing the ventilation therapy. If the patient was a previous tracheotomy patient, for example having been weaned from mechanical ventilation, then the tolerance test can be applied directly to the trachea through the tracheotomy. If the patient was a previous TTOT patient, for example with a 3mm transtracheal catheter, in the event the mature ostomy tract is too small for the TIJV catheter, then the tolerance test can be administered from the nasal mask, NGT, LMA or OPA as described previously, or alternatively the tolerance test is performed using a smaller than normal TIJV catheter that can fit in the existing ostomy. Or alternatively the tolerance test is delivered directly through the ostomy pre-existing from the transtracheal catheter using the same or similar transtracheal catheter, or a transtracheal catheter with the required sensors. Then if needed, a larger acclimation catheter and or sleeve is placed in the ostomy to dilate it and after the correct acclimation period the therapy is commenced.

Figure 38: In another embodiment of the present invention a special catheter is described with a stepped or tapered dilatation section. The catheter can be used to dilate the otomy to the appropriate amount during an acclimation period or during the therapeutic period by inserting to the appropriate depth, or can be used to successively dilate the otomy to larger and larger diameters. The catheter tapered section can be fixed or inflatable. Length and diameter markings are provided so that the proper diameter is used.

Figure 39 describes the overall invention, showing a wear-able ventilator 100 being worn by a patient Pt, which includes an integral gas supply 170, battery 101, volume reservoir/accumulator 168, on/off outlet valve 130, transtracheal catheter 500, a tracheal airflow breath sensor 101 and signal S, as well as an optional exhalation

counterflow unit 980, gas evaculation unit 982 and medicant delivery unit 984 and respective flow output or input 988, and a biofeedback signal 986.

It should be noted that the different embodiments described above can be combined in a variety of ways to deliver a unique therapy to a patient and while the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and combinations can be made without departing for the present invention. Also, while the invention has been described as a means for mobile respiratory support for a patient, it can be appreciated that still within the scope of this invention, the embodiments can be appropriately scaled such that the therapy can provide higher levels of support for more seriously impaired and perhaps non-ambulatory patients or can provide complete or almost complete ventilatory support for non-breathing or critically compromised patients, or can provide support in an emergency, field or transport situation. Also, while the invention has been described as being administered via a transtracheal catheter it should be noted that the ventilation parameters can be administered with a variety of other airway interface devices such as ET tubes, Tracheostomy tubes, laryngectomy tubes, cricothyrotomy tubes, endobronchial catheters, laryngeal mask airways, oropharyngeal airways, nasal masks, nasal cannula, nasal-gastric tubes, full face masks, etc. And while the ventilation parameters disclosed in the embodiments have been specified to be compatible with adult respiratory augmentation, it should be noted that with the proper scaling the therapy can be applied to pediatric and neonatal patients.

WHAT IS CLAIMED IS:

1. A ventilatory support apparatus, comprising:

a ventilator;

a ventilation gas delivery catheter adapted for connection to the ventilator;

a breath sensor in communication with the ventilator; and

an integrated ventilation gas reservoir to store a quantity of ventilation gas and integrated in the ventilator.

2. A ventilatory support apparatus, comprising:

(a) a ventilator;

(b) a catheter adapted to be indwelling in a patient's airway;

(c) a sensor adapted to be located in the patient's airway to measure tracheal airflow; and

(d) a ventilation gas source,

wherein a volume of ventilation gas is adapted to be delivered at a rate synchronized with the patient's spontaneous breathing and delivered during the patient's inspiratory phase.

3. An apparatus as in Claim 2 wherein the ventilator is configured to be worn by the patient.

4. An apparatus as in Claim 2 wherein the ventilator includes an integrated supply of oxygen volume.

5. An apparatus as in Claim 2 wherein the ventilator includes an integrated supply of liquid oxygen and means to convert the liquid oxygen into gaseous oxygen.

6. An apparatus as in Claim 2 wherein the ventilator includes an integrated oxygen generating system.

7. An apparatus as in Claim 2 wherein the ventilation gas volume to be delivered is 5-50% of a patient's natural tidal volume.

8. An apparatus as in Claim 2 wherein a ventilation gas driving pressure is 5-25psi.

9. An apparatus as in Claim 2 wherein a ventilation peak flow rate delivery is 15-35 liters per minute.

10. An apparatus as in Claim 2 wherein a ventilation gas delivery time is 0.1 to 0.8 seconds.

11. An apparatus as in Claim 2 wherein the catheter includes a catheter tip and a ventilation gas exit speed out of the catheter tip is 25-250 meters per second.

12. An apparatus as in Claim 2 wherein ventilation gas exit airflow dynamics are selected to cause 10-100% volume entrainment of gas from an upper airway into a lung with the ventilation gas.

13. An apparatus as in Claim 2 wherein a ventilation gas delivery amplitude is selected to cause a less negative pressure in a patient's lung during inspiration compared to a negative pressure during un-assisted breathing.

14. An apparatus as in Claim 2 wherein a ventilation gas delivery amplitude is selected to cause a positive pressure in a patient's lung during inspiration compared to a negative pressure during un-assisted breathing.

15. An apparatus as in Claim 2 wherein the breath sensor comprises two individual sensors used to obtain a comparison between the two individual sensors wherein a comparison is used to compensate for drifts and signal artifacts.

16. An apparatus as in Claim 15 wherein the individual sensor comparison is differentiated to correlate the signal to different parts of the breathing curve.

17. An apparatus as in Claim 2 wherein the ventilation gas source is a liquid oxygen system.

18. An apparatus as in Claim 2 wherein the ventilation gas source is a compressed oxygen gas source.

19. An apparatus as in Claim 2 wherein the ventilation gas source is an oxygen generating system.

20. An apparatus as in Claim 2 wherein the sensor comprises means to measure the strength and direction of tracheal airflow to deliver the ventilation gas after the inspriatory flow rate reaches a peak amplitude.

21. An apparatus as in Claim 2 wherein the sensor signal is correlated to respiratory muscle activity to provide means to deliver the ventilation gas after respiratory muscles reach their maximum work.

22. An apparatus as in Claim 2 comprising means for delivering gas after respiratory muscles reach their maximum work.

23. An apparatus as in Claim 2 comprising means for delivering the gas in multiple pulses during inspiration.

24. An apparatus as in Claim 2 comprising means for adjusting the ventilation gas delivery to occur at any time within the inspiratory phase, depending on the comfort and ventilatory needs of the patient, wherein a time in the inspiratory phase is determined by information from the breath sensor.

25. An apparatus as in Claim 23 wherein the adjustment means is capable of adjusting the ventilation gas delivery automatically by a physiological feedback mechanism.

26. An apparatus as in Claim 24 wherein the feedback mechanism is based on airway gas concentrations.

27. An apparatus as in Claim 24 wherein the feedback mechanism is based on depth of breathing.

28. An apparatus as in Claim 24 wherein the feedback mechanism is based on rate of breathing.

29. An apparatus as in Claim 24 wherein the feedback mechanism is based on pulse oximetry.

30. An apparatus as in Claim 23 wherein the adjustment means is capable of being made manually by the user.

31. An apparatus as in Claim 23 wherein the adjustment means is capable of being adjusted by a patient.

32. An apparatus as in Claim 23 wherein the adjustment means is capable of being adjusted by the clinician.

33. An apparatus as in Claim 2 wherein the ventilation gas delivery means is a primary ventilation gas delivery means and the apparatus further comprises means for delivering a secondary ventilation gas, the secondary gas delivery means comprising a lower gas flow rate compared to the primary ventilation gas delivery.

34. An apparatus as in Claim 32 comprising means to deliver the secondary ventilation gas early in inspiration.

35. An apparatus as in Claim 32 comprising means to deliver the secondary ventilation gas throughout inspiration.

36. An apparatus as in Claim 32 comprising means to deliver the secondary ventilation gas during exhalation.

37. An apparatus as in Claim 32 wherein the secondary ventilation gas displaces CO2 in the upper airway, such that the primary ventilation gas when delivered entrains air from the upper airway into the lower airways, wherein the entrained air is low in CO2, preferably at least 2% lower in CO2 compared to when the secondary ventilation gas is turned off.

38. An apparatus as in Claim 32 wherein the secondary ventilation gas comprises a high oxygen concentration, such as 50%-100% and preferably 80%-100%, and the primary ventilation gas comprises a lower oxygen concentration, such as 21%-60%.

39. An apparatus as in Claim 2 comprising means to adjust one of a pressure and a flow rate amplitude of the ventilation gas delivery.

40. An apparatus as in Claim 2 comprising means to adjust the shape of the ventilation gas delivery pressure or flow rate waveform into a desired waveform, including at least one of a sine wave, an ascending wave, a descending wave or a square wave, wherein the adjusting means comprises at least one of a valve, an orifice, a piston and a regulator.

41. An apparatus as in Claim 2 wherein the ventilation gas delivery comprises a primary ventilation gas delivery and the apparatus further comprises means to delivery gas into an airway during exhalation to provide a counter-resistance to exhaled flow, wherein the counter-resistance gas flow dynamics are selected to reduce airway collapse.

42. An apparatus as in Claim 40 comprising means to deliver the counter-resistance gas at a selectable strategic time within the expiratory phase including one of early in exhalation or late in exhalation.

43. An apparatus as in Claim 40 wherein the counter-resistance gas delivery occurs throughout exhalation.

44. An apparatus as in Claim 40 comprising means to deliver the counter-resistance gas in an oscillatory pattern.

45. An apparatus as in Claim 40 comprising means to deliver the counter-resistance gas in a turbulent pattern.

46. An apparatus as in Claim 40 comprising means to deliver the counter-resistance gas in a laminar pattern.

47. An apparatus as in Claim 40 wherein the counter-resistance gas delivery dynamics create a substantially uniform velocity profile in the airway.

48. An apparatus as in Claim 40 wherein the counter-resistance gas delivery dynamics create a substantially non-uniform velocity profile in the airway.

49. An apparatus as in Claim 2 comprising means, in addition to the primary ventilation gas delivery, to actively remove airway gas from the airway to reduce the CO2 content of gas in the airway.

50. An apparatus as in Claim 2 wherein the ventilation gas comprises at least one of following: oxygen, or helium-oxygen mixtures, or nitric oxide mixtures, or other therapeutic gases.

51. An apparatus as in Claim 2 comprising means to deliver a medicant.

52. An apparatus as in Claim 2 further comprising means to deliver one or more conjunctive therapies and (a) a secondary gas delivery; (b) a delivery of gas during exhalation to cause exhaled flow counter-resistance; (c) a removal of gas from the airway; (d) delivery of a therapeutic gas such as helium-oxygen or nitric oxide; (e) delivery of a medication.

53. An apparatus as in Claim 51 further comprising means to adjust the conjunctive therapies based on the needs of the patient, wherein the adjustment means can be manual or automatic based on a feedback, and wherein the adjustment means can permit turning the conjunctive therapy on or off or varying the amplitude of the conjunctive therapy.

54. An apparatus for providing ventilatory assistance to a patient wherein a gas volume is delivered into an airway of the patient via a catheter indwelling in the airway and wherein the apparatus is adapted such that:

(a) the gas volume is delivered at a rate in synchrony with the patient's spontaneous breathing and delivered during the patient's inspiratory phase;

(b) the gas volume delivered is 5-50% of the patient's natural tidal volume;

(c) a driving pressure in the catheter is 5-25psi, a peak flow rate of gas delivery is 15-35 liters per minute;

(d) a gas delivery time is 0.1 to 0.8 seconds;

(e) an exit speed of gas out of the catheter tip is 25-250 meters per second causing 10-100% volume entrainment; and

(f) the ventilator is synchronized with the patient's breathing pattern by using a breath sensor located in the airway of the patient to measure tracheal airflow

55. An apparatus as in Claim 2 wherein the ventilation gas source comprises a liquid oxygen supply source with a gaseous oxygen output orifice of greater than .100" diameter.

56. An apparatus as in Claim 2 wherein the ventilation gas source comprises a liquid oxygen supply unit comprising a heater to increase the rate of oxygen gas production.

57. An apparatus as in Claim 2 wherein the ventilation gas source comprises a liquid oxygen supply unit comprising a reservoir for storing oxygen converted to gaseous oxygen, wherein the reservoir stores greater than 80ml of gaseous oxygen.

58. An apparatus as in Claim 2 wherein the ventilation gas source comprises an oxygen supply unit, such as compressed oxygen gas or liquid oxygen, wherein the supply unit comprises multiple pressure regulator settings configured to regulate the gas at different gas pressures, wherein the regulator settings are adapted to be selectable by the user for regulating a pressure of a gaseous phase oxygen at different pressure levels.

59. An apparatus as in Claim 2 comprising means to regulate pressure output from the gas source, an accumulator to accumulate gas at the regulated pressure, an on/off valve for controlling flow output from the accumulator to the patient and the sensor comprises breath sensors to determine the breath phase of the patient.

60. An apparatus as in Claim 2 wherein the ventilation gas source comprises a compressed oxygen gas canister comprising a regulator wherein the regulator comprises a gas output orifice configured to provide an output of 10-40 psi and greater than 6 liters per minute.

61. An apparatus as in Claim 2 wherein the ventilation gas source comprises an integral oxygen generator unit, a pressure amplifier, a pump to boost the pressure amplifier, and a gas reservoir.

62. An apparatus as in Claim 60 wherein the pressure amplifier is pneumatic.

63. An apparatus as in Claim 60 wherein the pressure amplifier is electro-pneumatic.

64. An apparatus as in Claim 60 wherein the pressure amplifier amplifies pressure from ambient pressure to at least 10psi and preferably to at least 20psi.

65. An apparatus as in Claim 60 wherein the pressure amplifier comprises two sections, a first gas input section and a second gas output section, wherein the cross-sectional area of the input section is smaller than the cross-sectional area of the output section, wherein source gas pressure is brought into the first section and expelled through the second section.

66. An apparatus as in Claim 2 further comprising a gas accumulator, wherein the accumulator accumulates the volume of gas being delivered to the patient in one breath for each breath delivered.

67. An apparatus as in Claim 65 wherein the accumulator is a cylinder with a stroking piston.

68. An apparatus as in Claim 2 further comprising means to draw in ambient air in to a ventilation gas delivery circuit to provide the ability to deliver ventilation gas to the patient with oxygen concentrations from 21% to 100%.

69. An apparatus as in Claim 67 wherein the means to draw in ambient air comprises a Venturi unit wherein the Venturi is created by ventilation gas flow dynamics in the ventilation gas delivery circuit.

70. An apparatus as in Claim 67 wherein the ambient air is drawn into a gas volume accumulator, wherein the accumulator includes a stroking piston

71. An apparatus as in Claim 67 wherein the ambient air is drawn in by a pump.

72. An apparatus as in Claim 2 wherein the ventilator comprises an alternating cylinder design, wherein during a breath cycle of the patient, a first cylinder compresses with pressurized ventilation gas while a second cylinder decompresses pressurized ventilation gas to the patient, and wherein during a subsequent breath cycle of the patient, the first cylinder decompresses to the patient and the second cylinder re-pressurizes from the gas source.

73. An apparatus as in Claim 71 wherein the cylinders include a stroking piston.

74. An apparatus as in Claim 2 comprising a ventilation gas delivery circuit including: (a) an array of accumulators; (b) an array of gas flow orifices; (c) accumulator outlet valves to open or close the output of the accumulators; (d) means to select the flow orifice that the ventilation gas travels through; and (e) means to select and open or close the accumulator outlet valves to control which accumulator outlet is open and which are closed.

75. An apparatus as in Claim 73 wherein the accumulators are arranged in parallel.

76. An apparatus as in Claim 73 wherein the accumulators comprise multiple volume sizes.

77. An apparatus as in Claim 73 wherein the orifices comprise different orifice dimensions.

78. An apparatus as in Claim 2 further comprising a gas volume accumulator comprising: (a) a cylinder, (b) a stroking piston within the cylinder, (c) an inlet and outlet port on one side of the piston and an spring element on the opposite side of the piston, (d) a valve means to control the filling and emptying of the cylinder, wherein the spring element comprises a spring force sufficient to accelerate the emptying of the gas out of the cylinder to the patient.

79. An apparatus as in Claim 2 further comprising a gas volume accumulator comprising a cylinder with an internal stroking piston, wherein a geometric volume of the cylinder is adjustable.

80. An apparatus as in Claim 78 wherein the cylinder volume adjustment means is a moveable end-cap on one end of the cylinder wherein the end-cap slides axially in the inner diameter of the cylinder.

81. An apparatus as in Claim 78 wherein the cylinder volume adjustment is adjusted manually, for example by rotation of a knob.

82. An apparatus as in Claim 78 wherein the cylinder volume adjustment is adjusted automatically, for example by use of a motor.

83. An apparatus as in Claim 78 wherein the cylinder volume adjustment is monitored by use of a position scale, such as an axial scale to determine the position of said end-cap, or a radial scale to determine the position of said knob.

84. An apparatus as in Claim 78 wherein the cylinder volume adjustment is monitored by use of a position sensor, such as an axial sensor to determine the position of the end-cap, or a radial sensor to determine the position of the knob.

85. An apparatus as in Claim 2 further comprising valves and control means to shape a ventilation gas delivery profile as desired, such as a sine wave, square wave or accelerating or decelerating wave.

86. An apparatus as in Claim 2 further comprising a gas accumulator wherein the gas accumulator is shaped non-cylindrically.

87. An apparatus as in Claim 2 further comprising a gas accumulator wherein the gas accumulator is shaped with a concave curve.

88. An apparatus as in Claim 2 further comprising a gas accumulator wherein the gas accumulator comprises a bone-shaped cross section.

89. An apparatus as in Claim 2 further comprising a gas accumulator wherein the gas accumulator comprises an array of separate interconnected cylinders.

90. An apparatus as in Claim 2 further comprising a gas accumulator wherein the gas accumulator is comprised of tubing.

91. An apparatus as in Claim 2 wherein a ventilation gas supply reservoir is configured non-cylindrically, such as but not limited to a concave shape, a bone-shaped cross section, an array of interconnected cylinders, or curved conduit.

92. An apparatus as in Claim 2 wherein the catheter includes a catheter tip that is restricted to provide the desired amount of gas exit speed, typically 50 to 300 meters per second and preferably 100-250 meters per second.

93. An apparatus as in Claim 91 wherein the catheter tip is restricted to produce the desired amount of entrainment of upper airway air, typically 10-200% and preferably 25-100%.

94. An apparatus as in Claim 91 wherein the catheter tip restriction is constant.

95. An apparatus as in Claim 91 wherein the catheter tip restriction is variable.

96. An apparatus as in Claim 91 wherein the catheter tip restriction is variable wherein the restriction is varied by the use of an adjustable member in the gas flow lumen of the catheter tip.

97. An apparatus as in Claim 95 wherein the adjustable member adjusts radially to decrease or increase the gas flow lumen diameter.

98. An apparatus as in Claim 95 wherein the adjustable member axially slides to actuate an increase or decrease in the gas flow lumen diameter.

99. An apparatus as in Claim 2 wherein the gas flow lumen is restricted to produce an exit speed of typically 50-300 meters per second and preferably 100-250 meters per second.

100. An apparatus as in Claim 98 wherein the gas flow lumen tip diameter is restricted to an inner diameter of 0.5mm to 2.0mm, and preferably 1.0mm to 1.6mm.

101. An apparatus as in Claim 2 comprising a main ventilation gas flow opening at the distal tip to deliver the main ventilation gas toward the lung, and comprising a secondary opening configured to direct delivery of the secondary gas upward toward the larynx.

102. An apparatus as in Claim 2 comprising gas flow ports near the distal tip wherein the ports are configured to allow gas to exit the catheter multi-directionally, wherein the ports and multidirectional flow is selected to produce a uniform or semi-uniform velocity profile in the airway.

103. An apparatus as in Claim 2 comprising a generally 360° curve at its end which is inserted into the trachea, wherein the catheter gas delivery lumen is blocked to gas flow at the tip of the catheter, and comprising a gas exit port located on the curved section of the catheter at a location to direct the exiting gas flow toward the lung, and wherein the radius of the curve positions a portion of the curve against the anterior tracheal wall.

104. An apparatus as in Claim 2 comprising a generally a 540° curve at its end which is inserted into the trachea, wherein the curve positions the tip of the catheter pointing toward the lung, wherein the radius of the curve positions a portion of the curve against the anterior and posterior wall of the trachea.

105. An apparatus as in Claim 2 comprising an outer cannula sleeve, wherein the outer cannula sleeve comprises a stomal sleeve, and wherein the outer cannula sleeve directs the catheter tip to the center of the trachea.

106. An apparatus as in Claim 2 comprising (a) a spacer positioned inside the trachea used to space the catheter away from the stomal tissue; (b) a curve configured to position a portion of the distal section of the catheter against the anterior tracheal will; (c) a curve to position the tip of the catheter away from the airway wall and directed toward the lungs.

107. An apparatus as in Claim 2 with a distal section that is inserted into a patient wherein the inserted section is comprised of a soft material of 20-80 Shore A durometer and preferably 30-50 Shore A durometer and further comprising a rigid member imbedded into the construction to provide the soft material semi-rigidity.

108. An apparatus as in Claim 106 wherein the rigid member is a spring material.

109. An apparatus as in Claim 106 wherein the rigid member is a shape memory alloy material.

110. An apparatus as in Claim 106 wherein the rigid member is a malleable material.

111. An apparatus as in Claim 2 wherein the catheter comprises thermally responsive material in its construction which causes a change from a first shape to a second shape of the catheter when reaching body temperature, wherein the first shape is configured to aide in insertion of the catheter and the second shape is configured to aide in atraumatic positioning of the catheter in the airway and to direct the gas exit of the catheter to the lungs.

112. A ventilation catheter as in Claim 2 wherein the catheter patient end is configured to connect to a standard 15mm connector a tracheal tube, such as a tracheostomy tube or laryngectomy tube, and comprising a sensor extension that extends into the shaft of the tracheal tube or beyond the distal tip of the tracheal tube.

113. An apparatus as in Claim 2 comprising at its distal tip a radially expandable or compressible basket configured to anchor the catheter in the airway and position the tip of the catheter generally in the center of the airway.

114. An apparatus as in Claim 2 comprising a outer diameter mating stomal sleeve configured for insertion into the stomal tract and for insertion of the catheter through the sleeve, wherein the sleeve further comprises a spacer on its distal end configured to position the catheter tip away from the anterior tracheal wall.

115. An apparatus as in Claim 2 comprising: (a) a distal section inserted into the trachea wherein the distal inserted section comprises a generally 90° curve to

position the tip of catheter to be pointing toward the lungs; (b) an flange placed on the catheter shaft positioned outside the patient comprising means to axially adjust the placement of the flange on the catheter shaft and comprising means to lock the axial position of flange on the catheter shaft; (c) length markings on the catheter shaft to correspond to the flange position.

116. An apparatus as in Claim 2 comprising a compressible member for sealing with and securing to the stomal tract.

117. An apparatus as in Claim 2 comprising a signal element recognizable by the ventilator, wherein the signal element defines a therapeutic attribute of the catheter, such as patient compatibility, intended disease state, or length of usage of therapy by the patient, and wherein the ventilator comprises the ability to recognize the signal element and alter its output based on the signal.

118. A stomal sleeve comprising an external flange on a first proximal end and an internal flange on a second distal end, wherein the internal flange is fold-able and compressible into a low profile state prior to insertion, and can be unfolded and released into its expanded state after insertion into the stoma, and can further be re-folded into its low profile state for removal from the stoma.

119. An apparatus as in Claim 2 wherein the breath sensor comprises two sensors wherein a first sensor is a negative coefficient thermistor and a second sensor is a positive coefficient thermistor.

120. An apparatus as in Claim 2 wherein the breath sensor comprises two pair of thermistors, wherein each pair is connected to a wheatstone bridge circuit, and wherein one par of thermistors are negative coefficient thermistors and the second pair of thermistors are positive coefficient thermistors.

121. An apparatus as in Claim 2 wherein the breath sensor comprises at least two thermistors, wherein at least one thermistor is located on the surface of the catheter facing the larynx and at least one thermistor is located on the surface of the catheter facing the lungs.

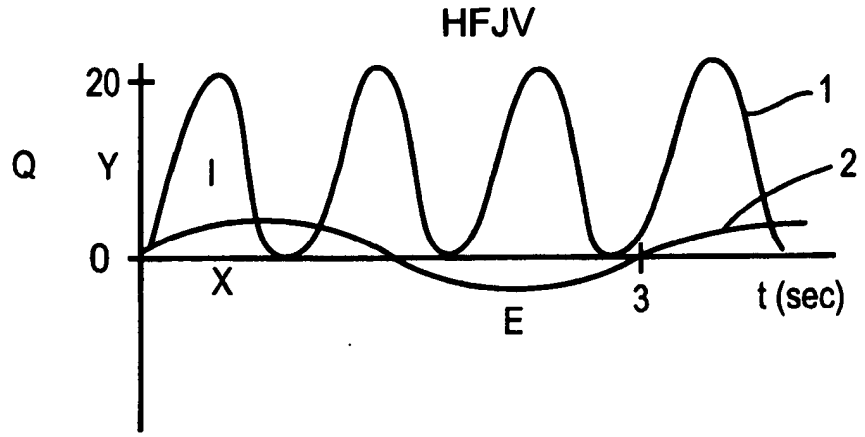


FIG. 1a

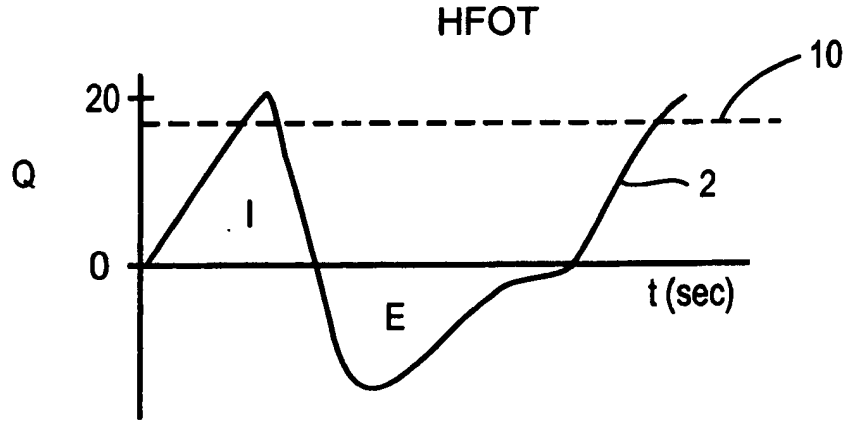


FIG. 1b

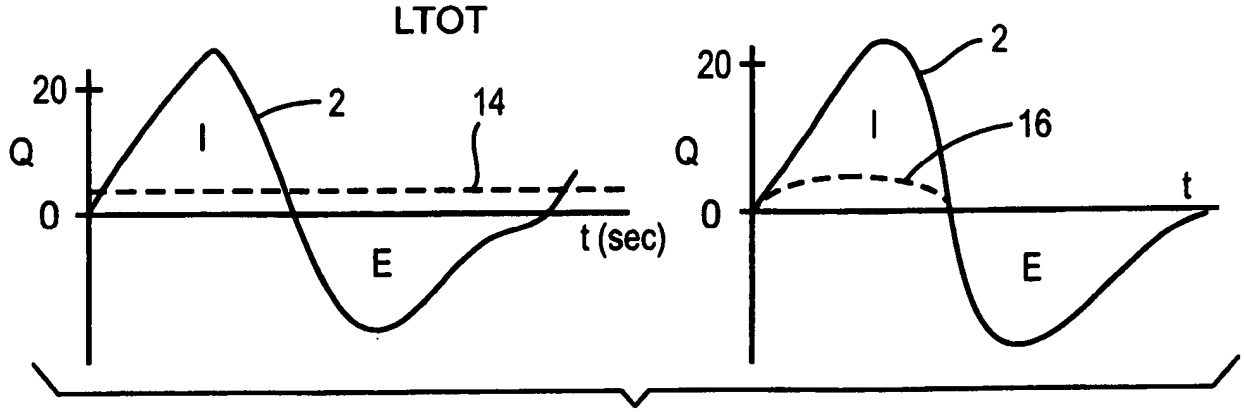


FIG. 1c

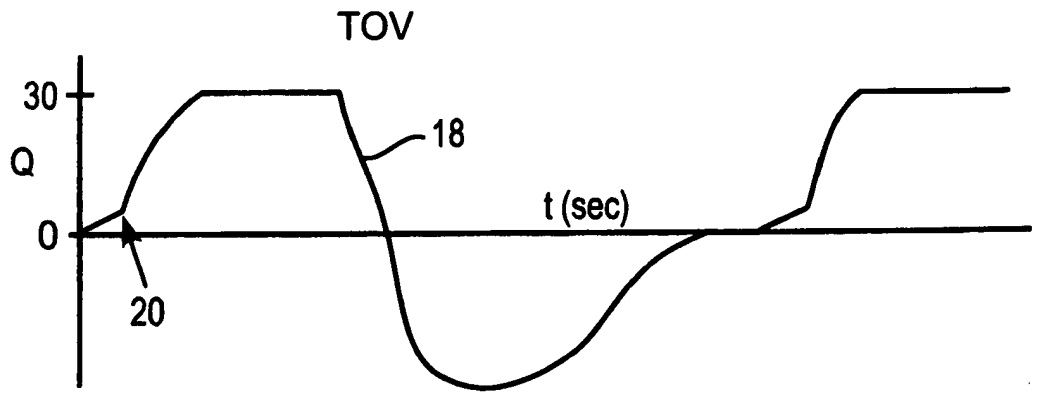


FIG. 1d

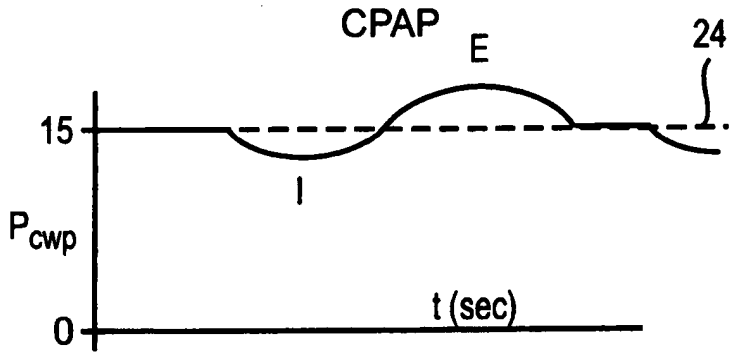


FIG. 1e

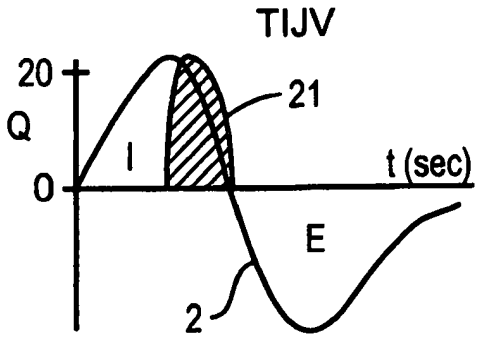


FIG. 1f

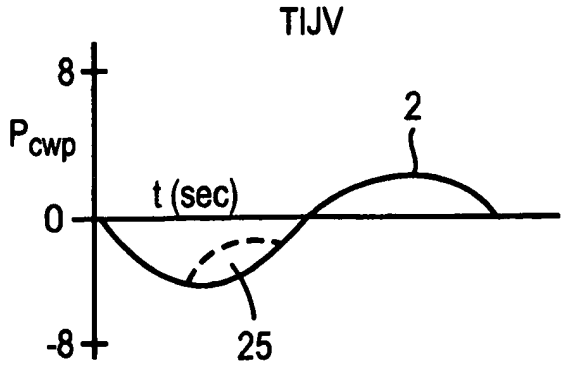


FIG. 1g

FIG. 2a

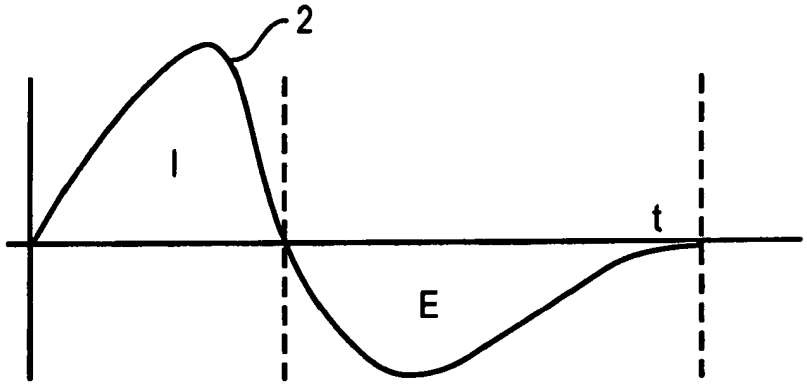


FIG. 2b

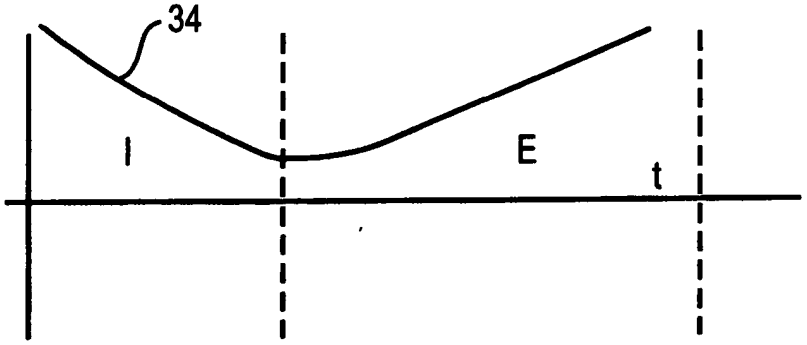


FIG. 2c

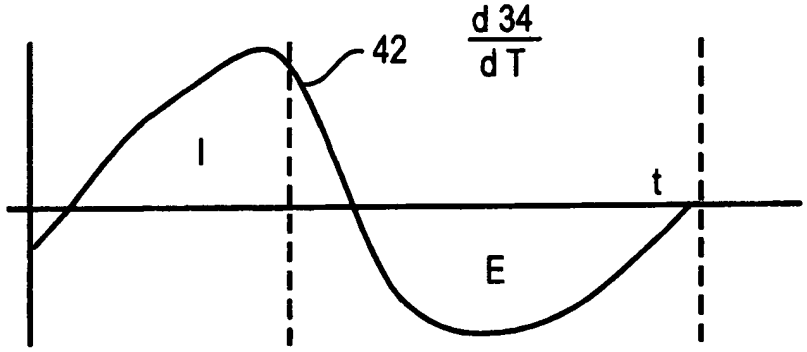
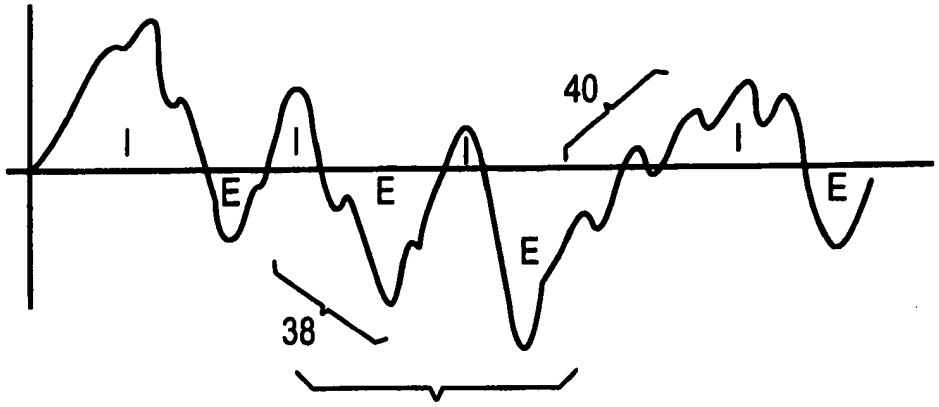


FIG. 2d



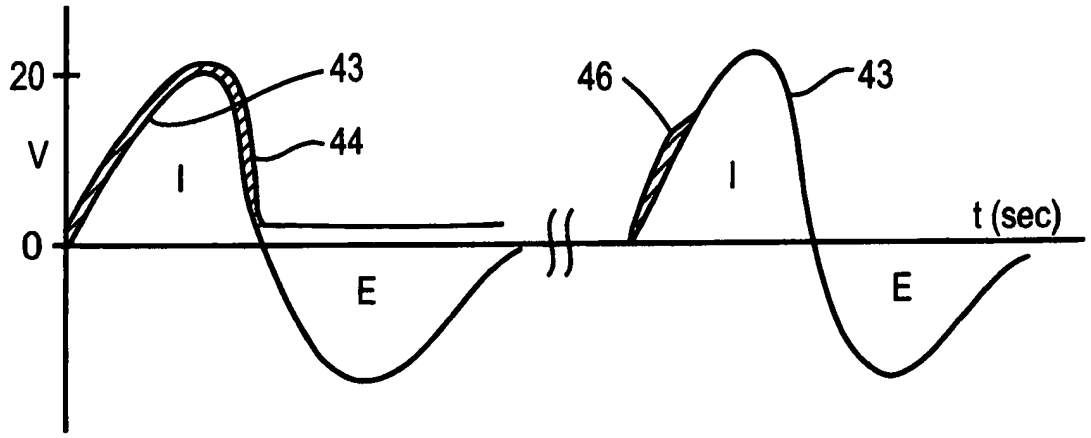


FIG. 3

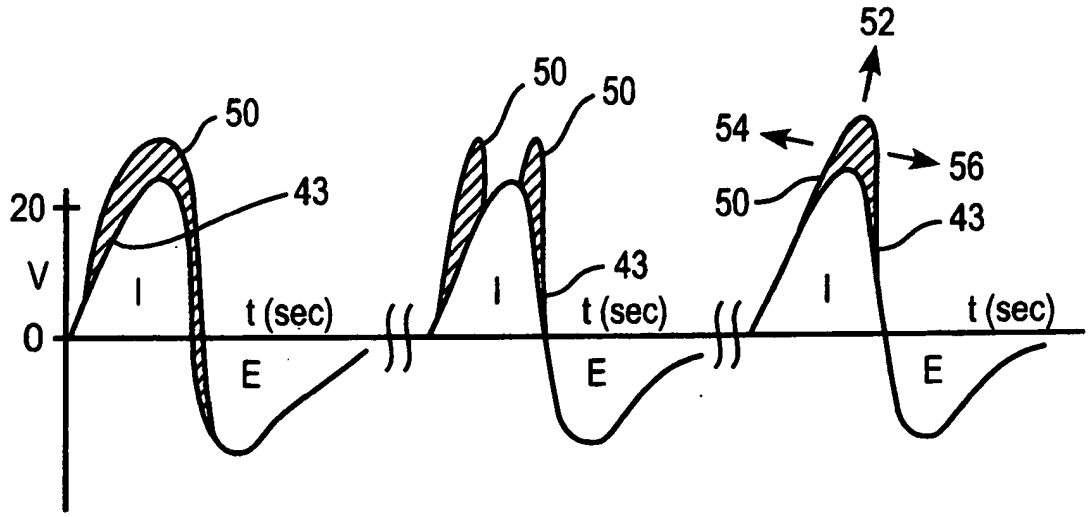


FIG. 4a

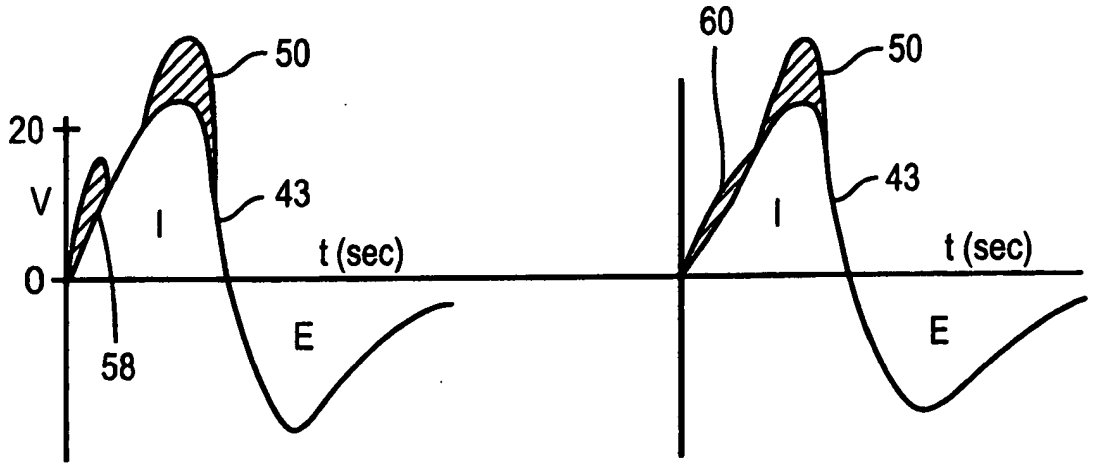


FIG. 4b

FIG. 4c

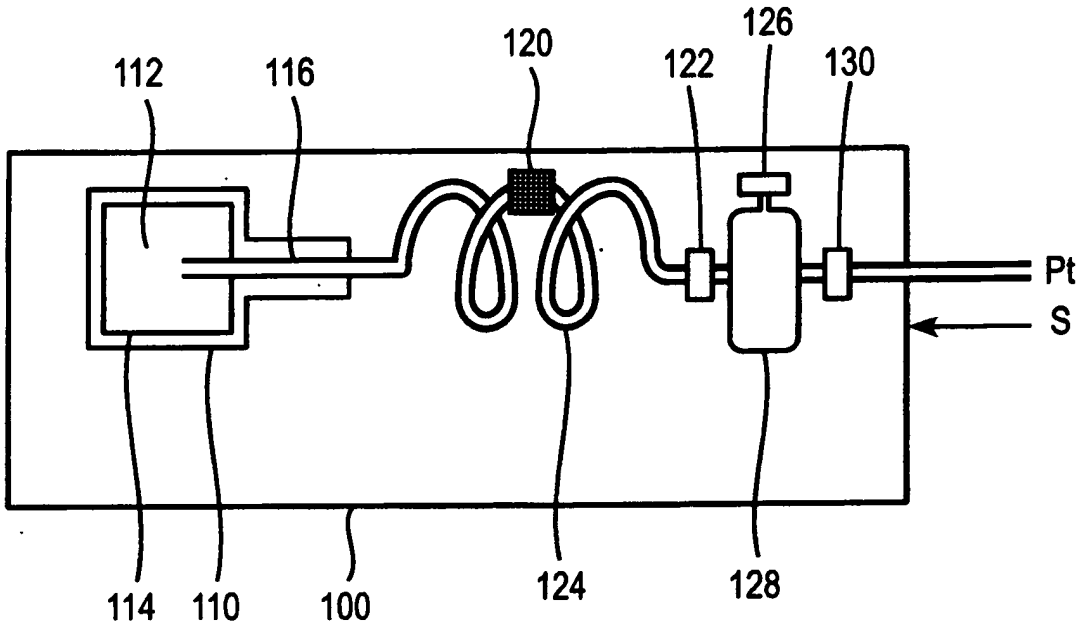

112
116
120
122
126
130
Pt
S
114
110
100
124
128

FIG. 5

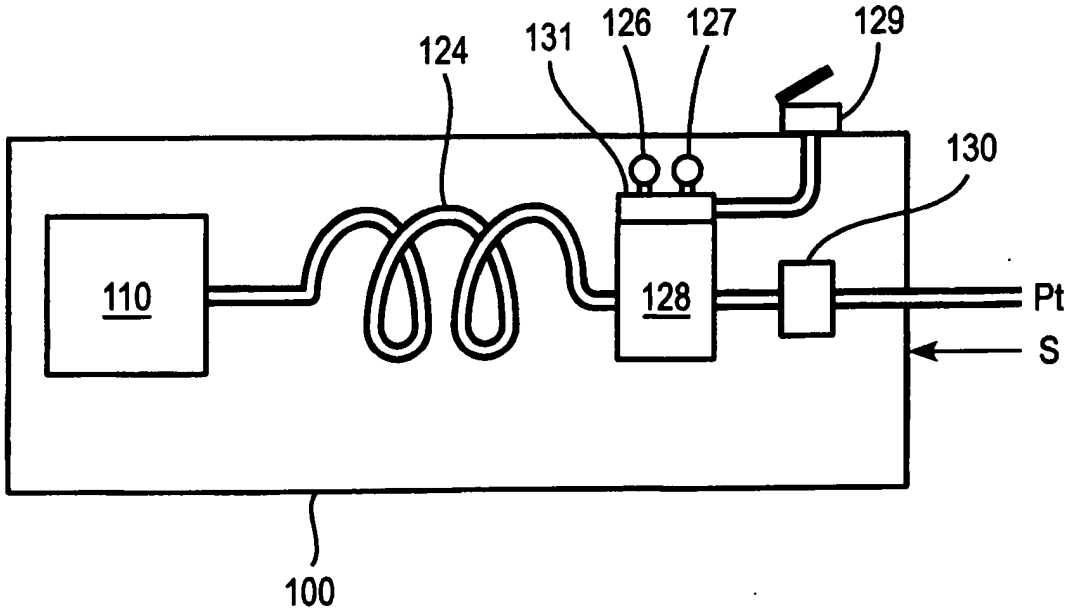

124
131
126
127
129
130
110
128
Pt
S
100

FIG. 6

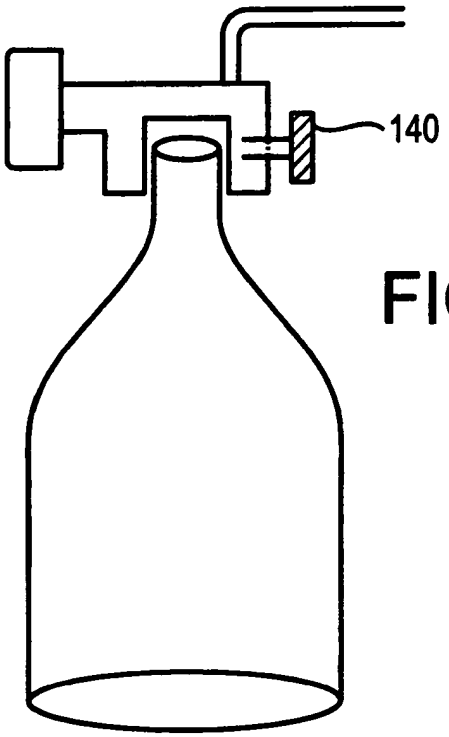


FIG. 7

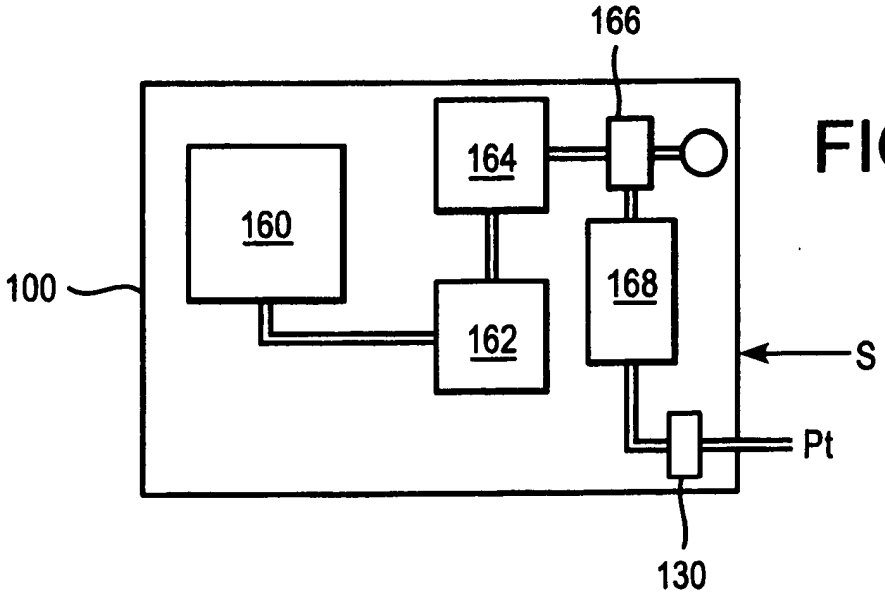


FIG. 8

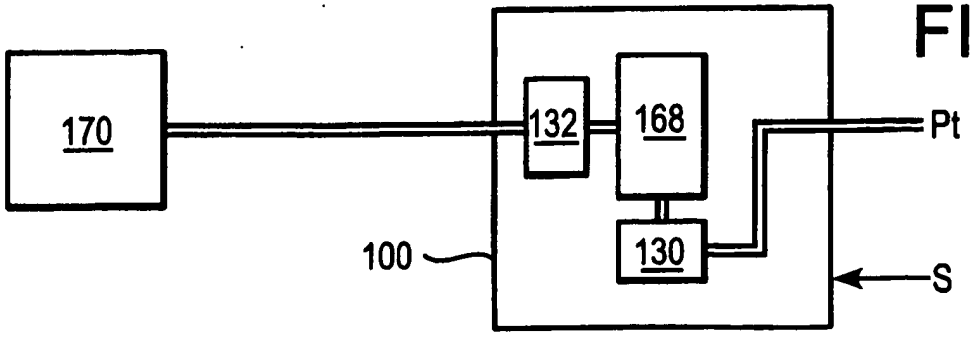
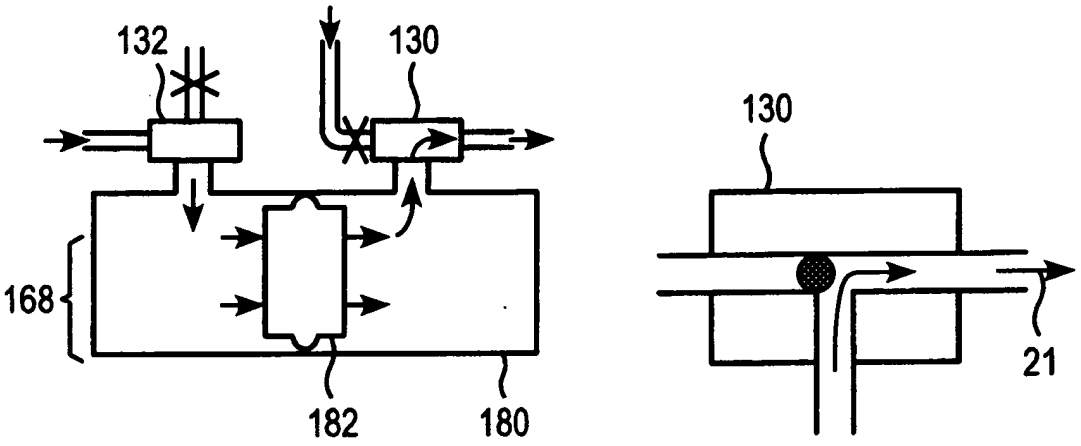


FIG. 9

FIG. 10a



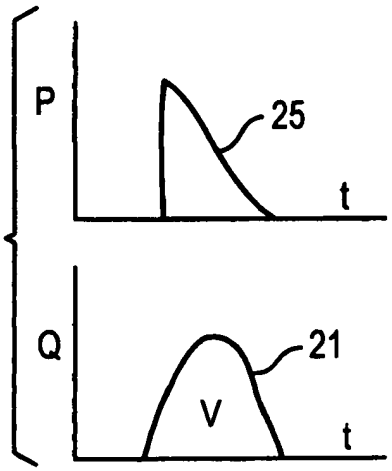


FIG. 10b

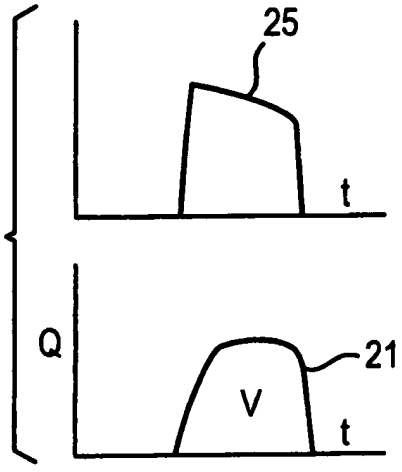


FIG. 10c

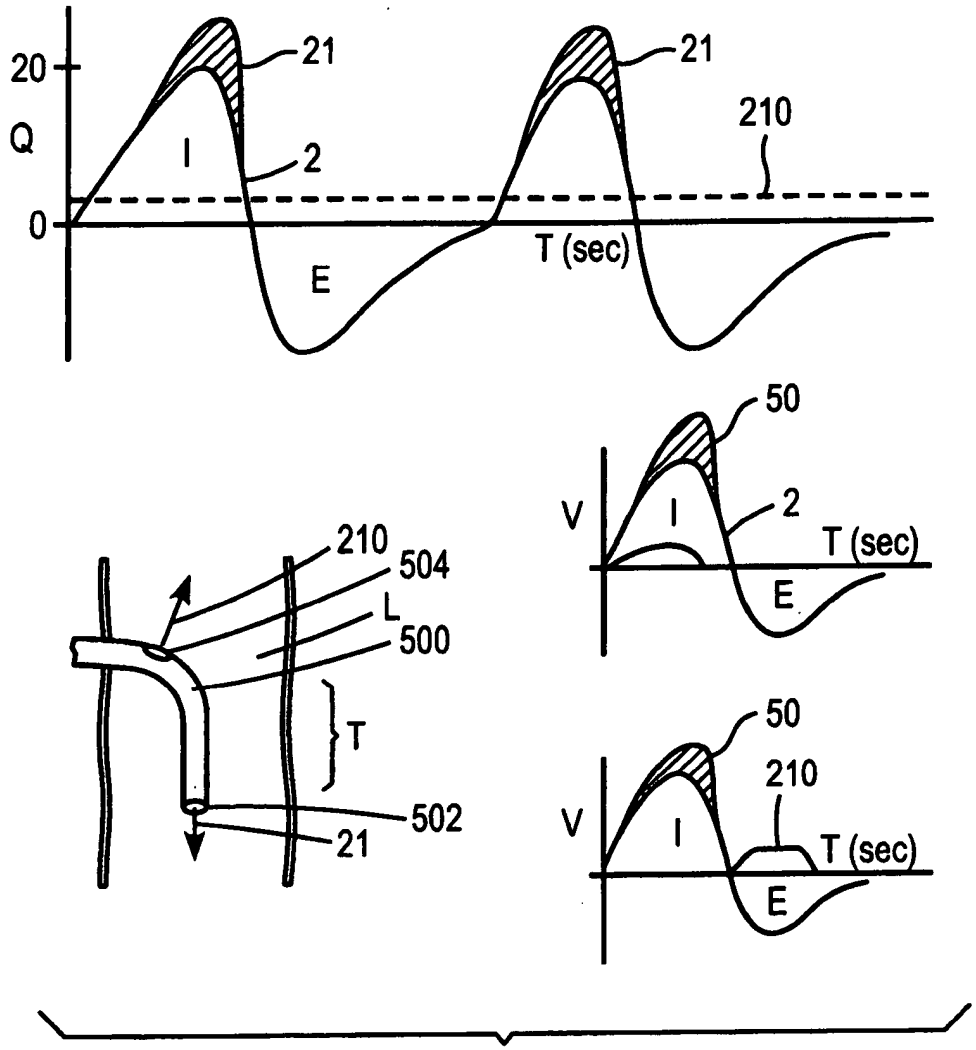

20
Q
0
21
I
2
E
T (sec)
21
210
50
V
I
2
T (sec)
E
210
504
L
500
T
502
21
50
V
I
210
T (sec)
E

FIG. 11

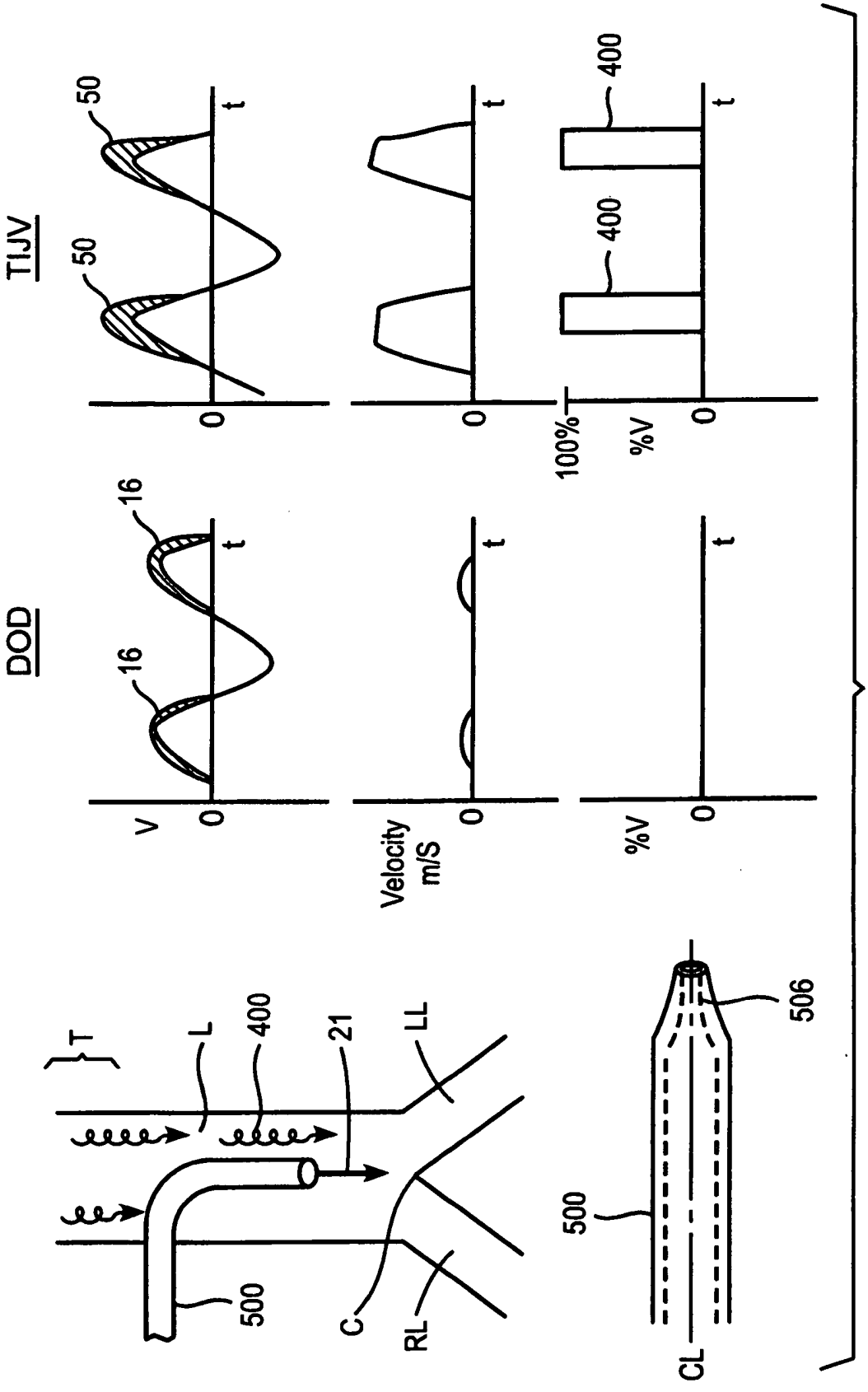

TIJV
DOD
50
50
16
16
t
0
V
Velocity m/S
%V
100%
400
400
T
L
400
21
LL
500
C
RL
506
CL

FIG. 12

FIG. 13

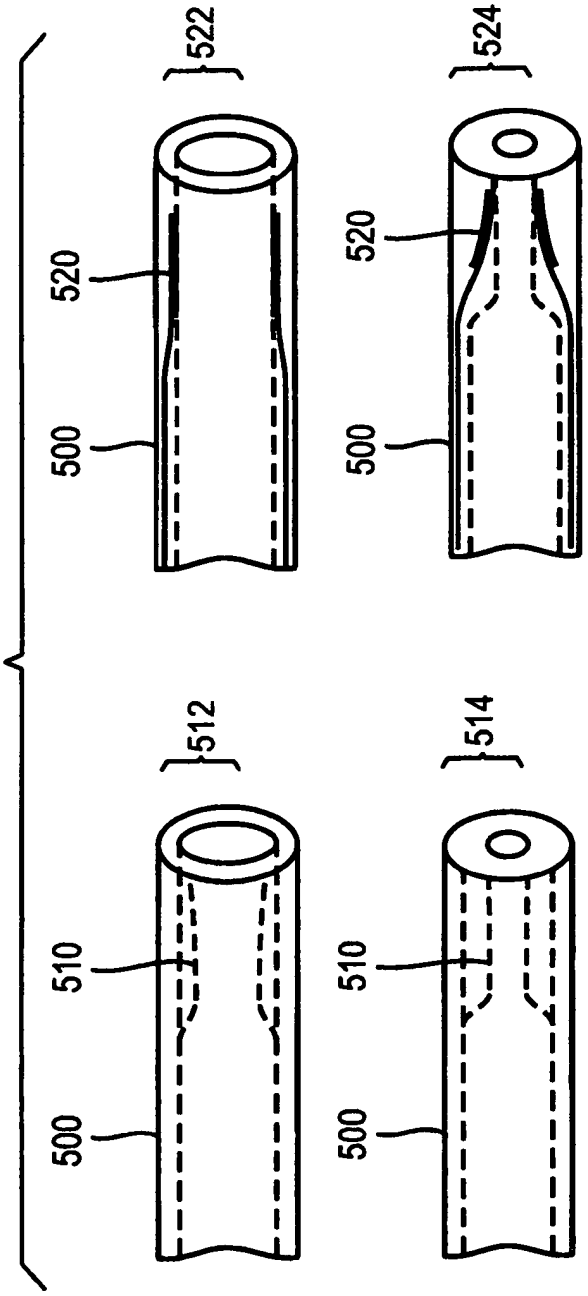
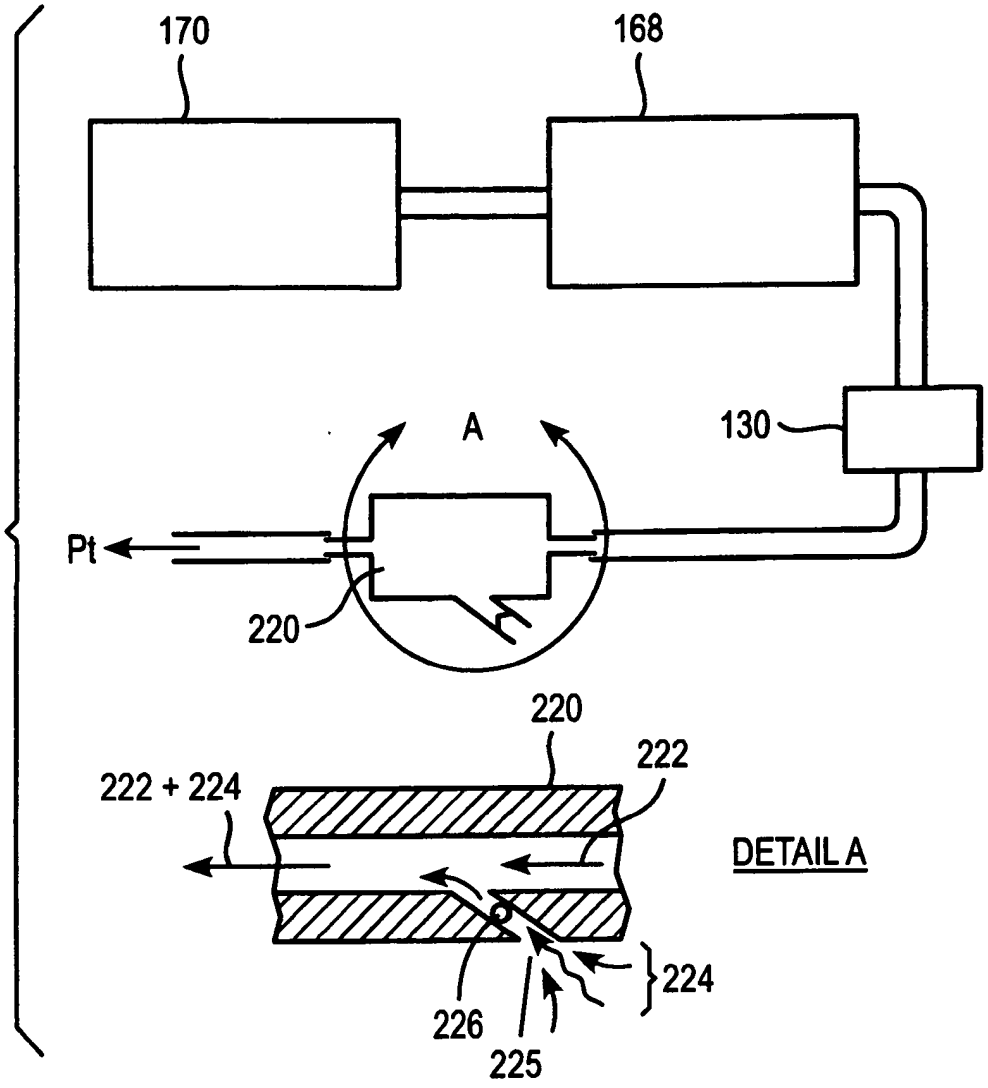


FIG. 14a



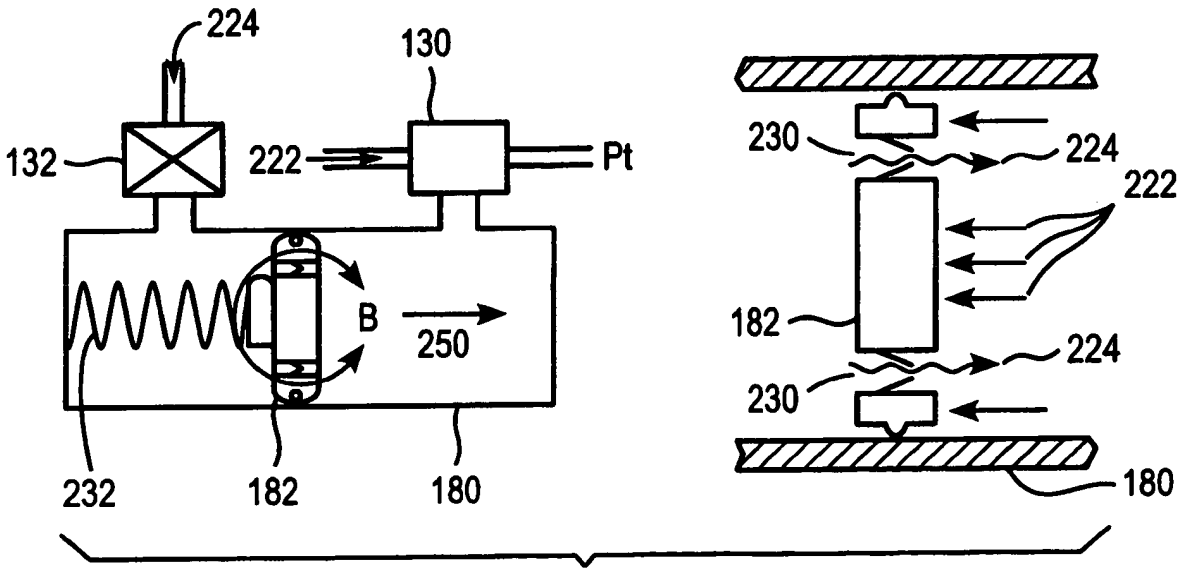


FIG. 14b

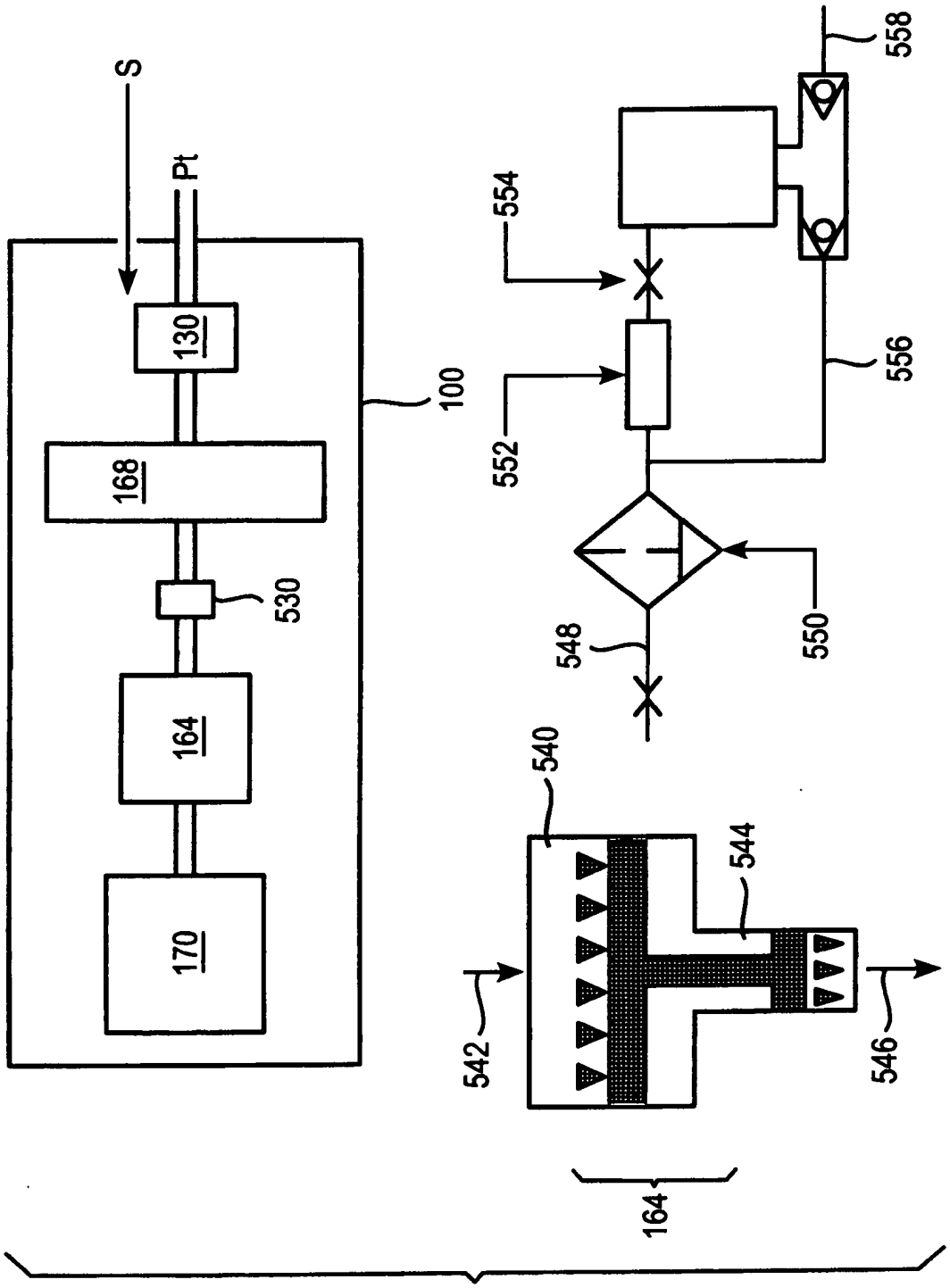

S
Pt
130
168
530
164
170
100
558
554
556
552
550
548
540
544
542
546
164

FIG. 15

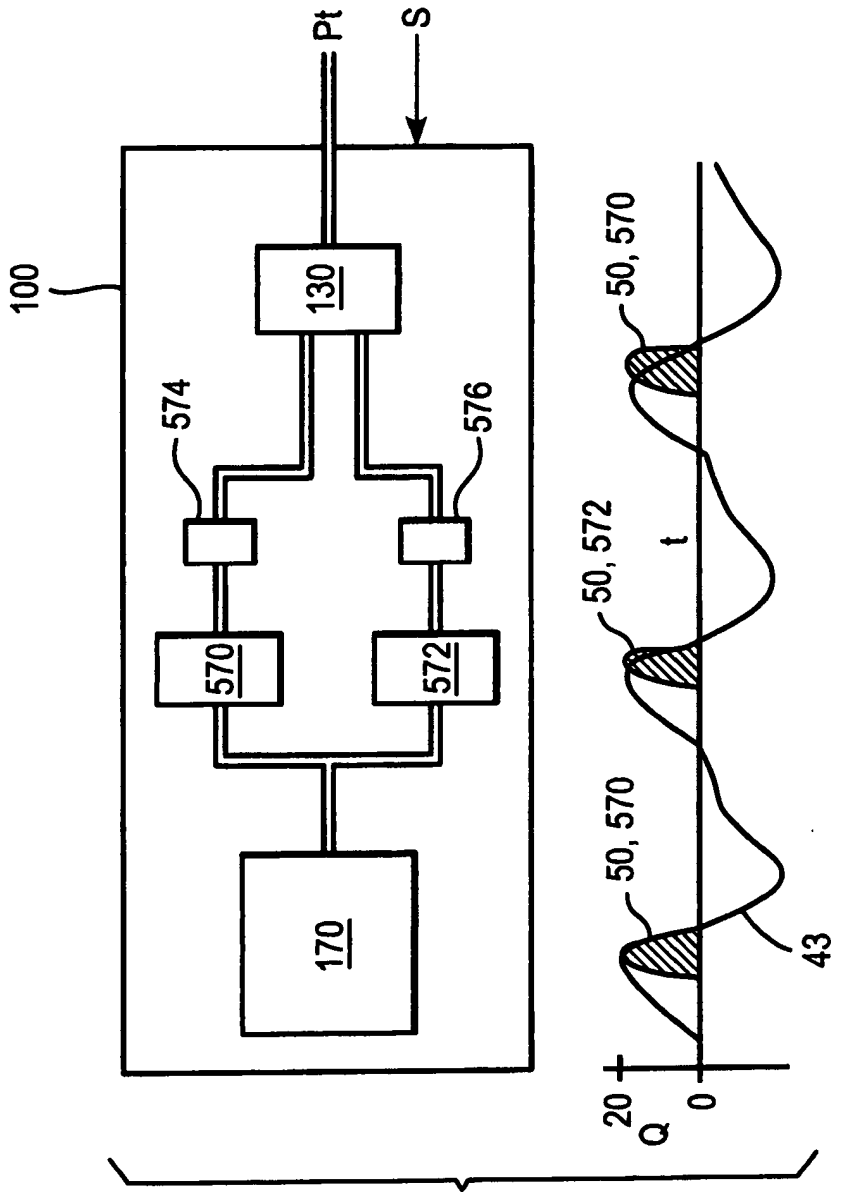


FIG. 16

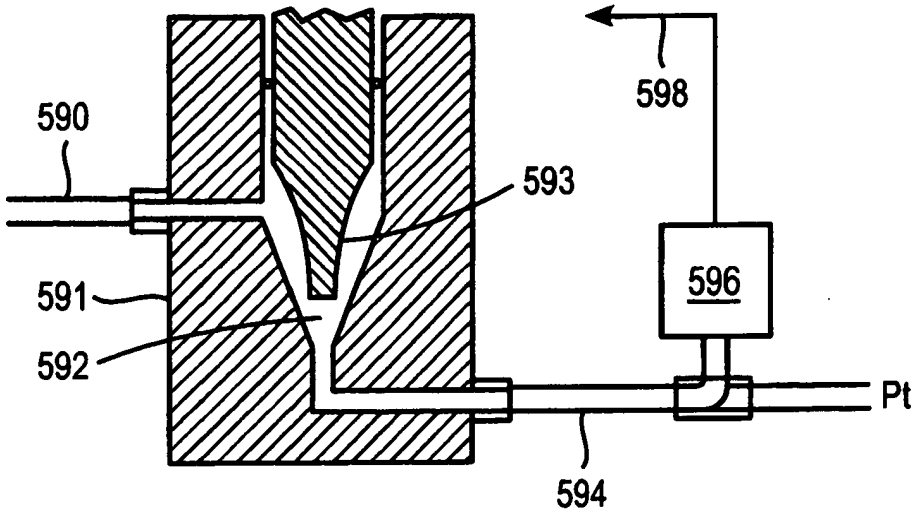


FIG. 17a

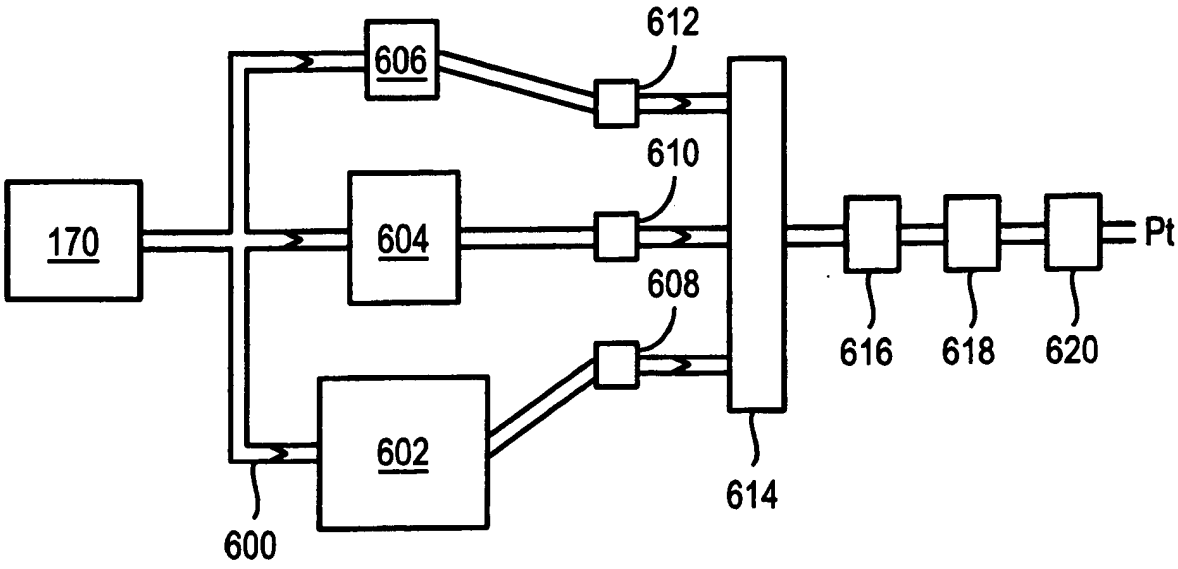


FIG. 17b

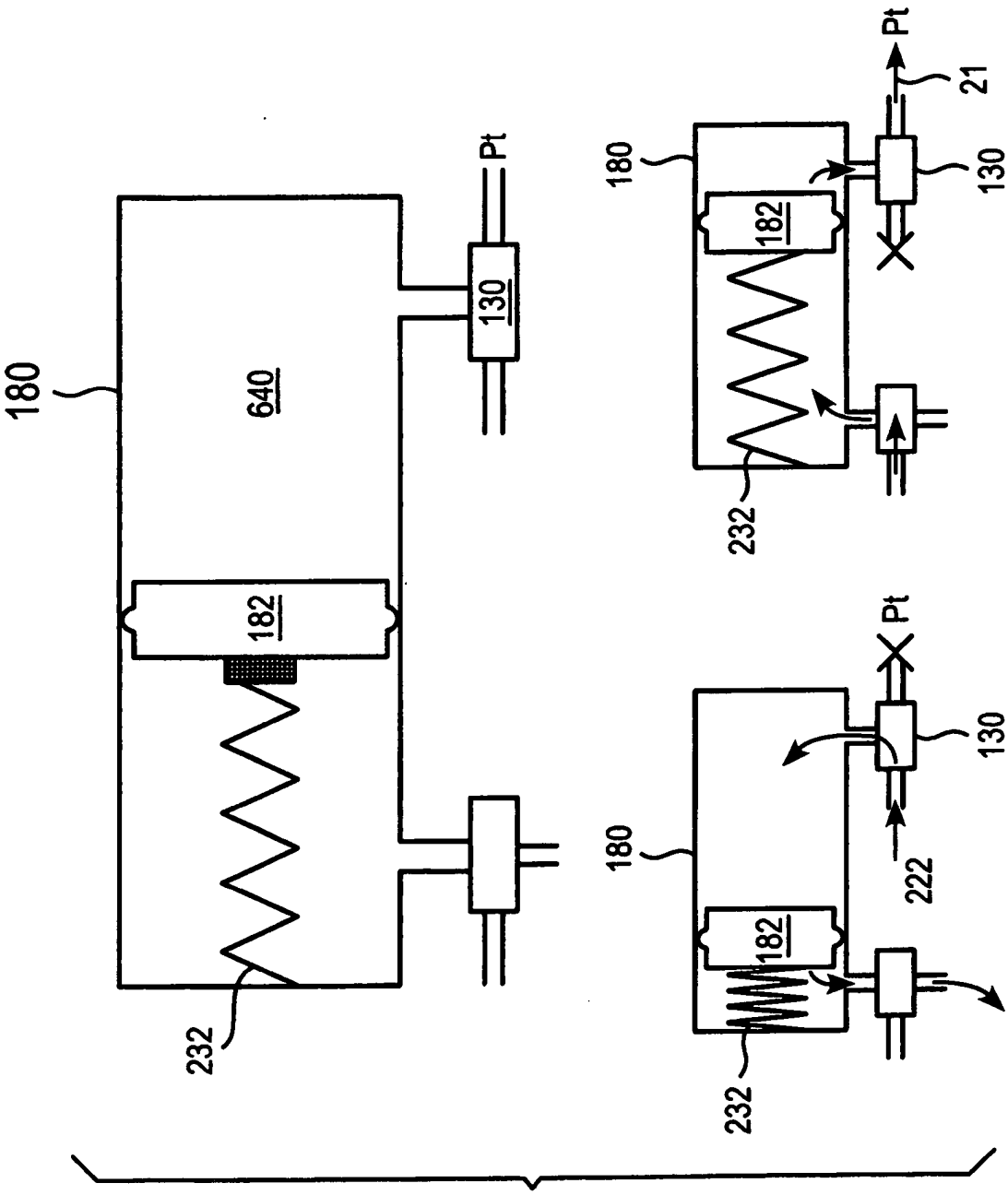

180
640
182
130
Pt
232
180
182
130
Pt
21
232
180
182
130
Pt
222
232

FIG. 18

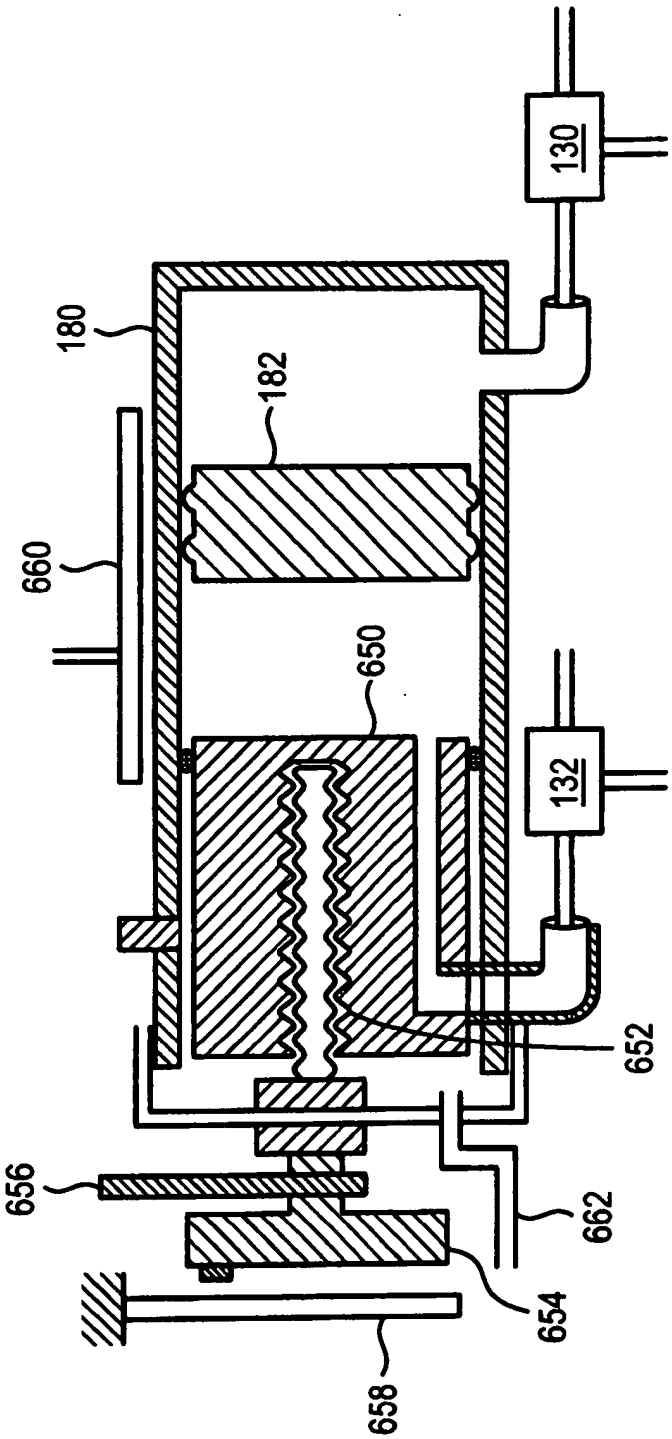


FIG. 19

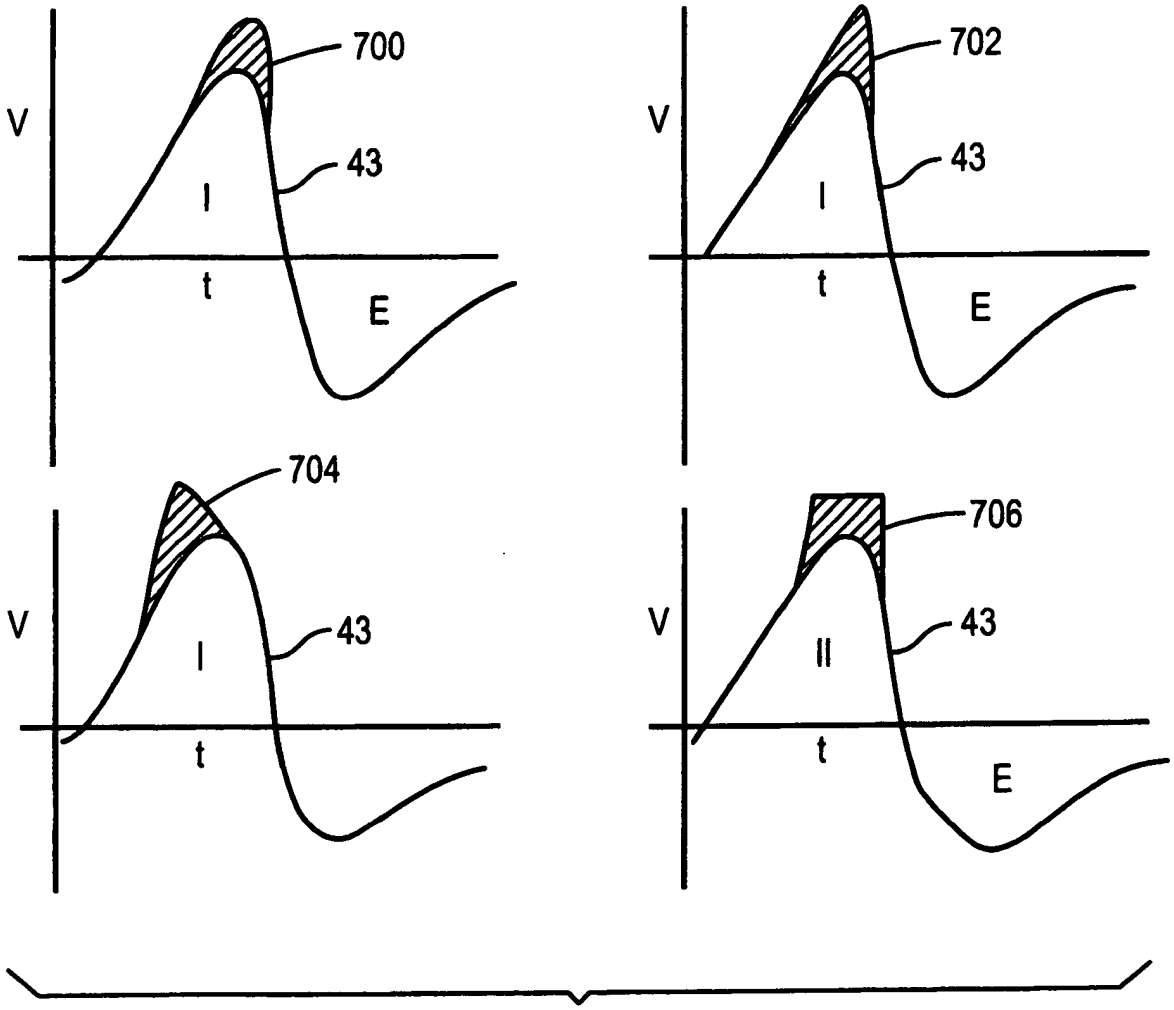


FIG. 20

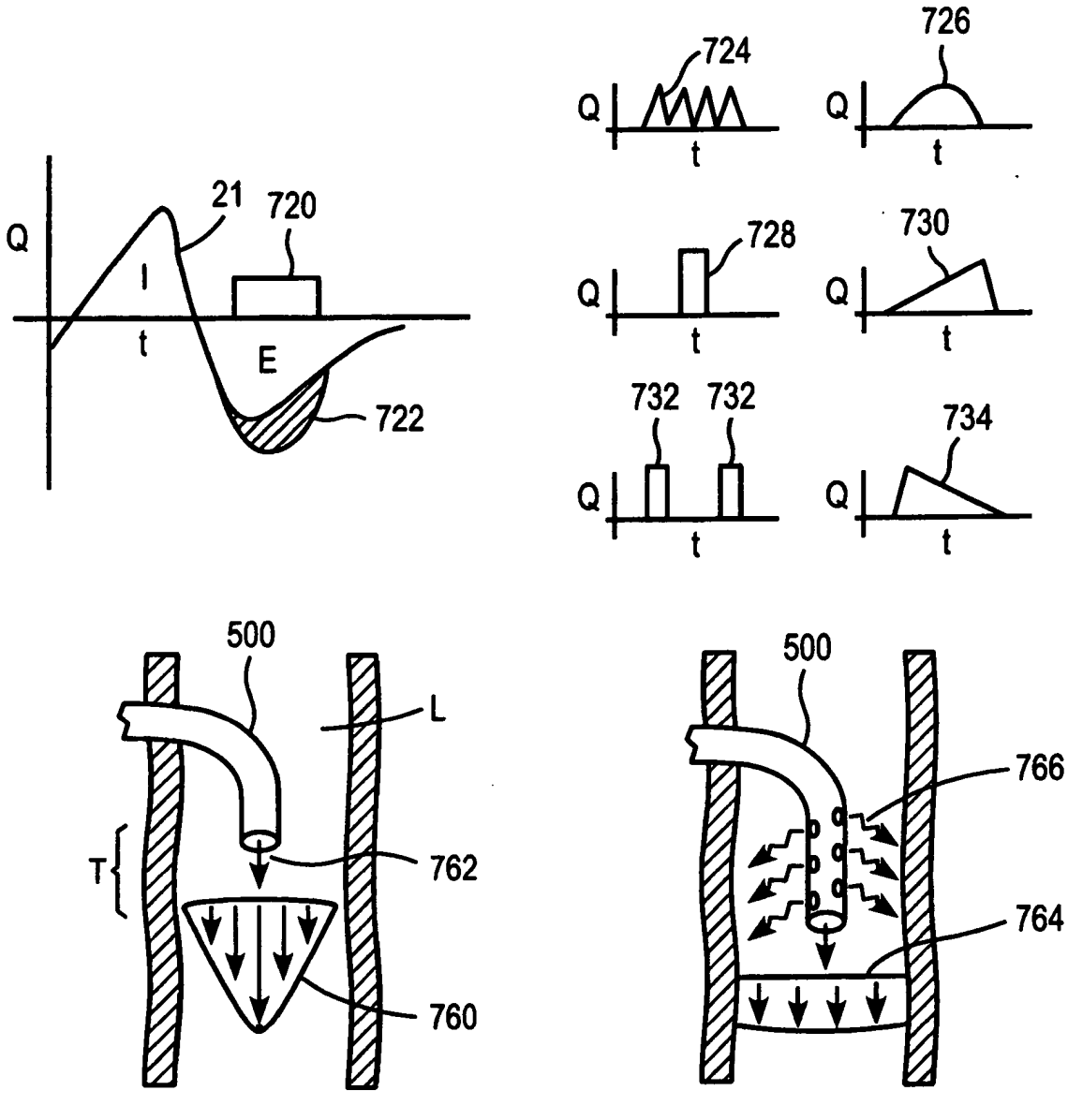

Q
21
720
I
t
E
722
724
726
728
730
732
732
734
500
L
T
762
760
766
764

FIG. 21

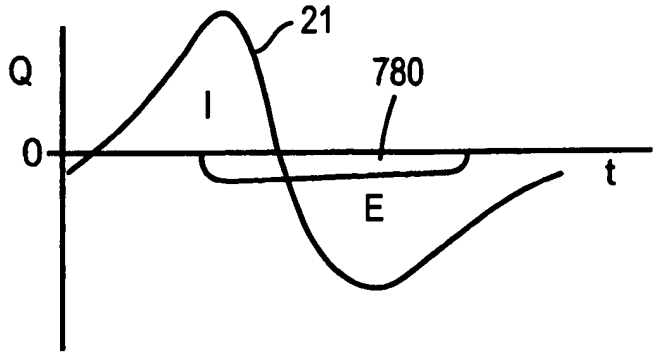


FIG. 22

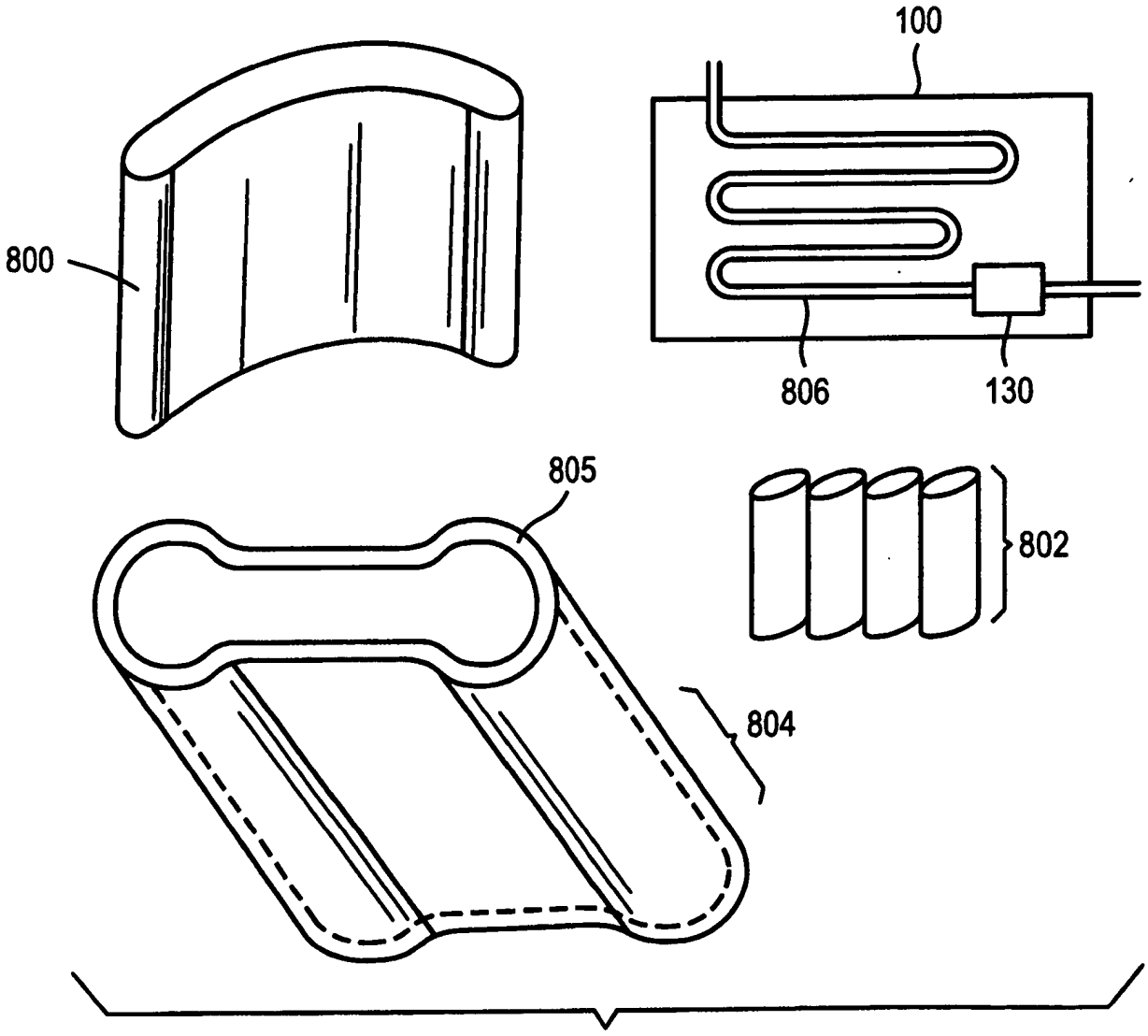


FIG. 23

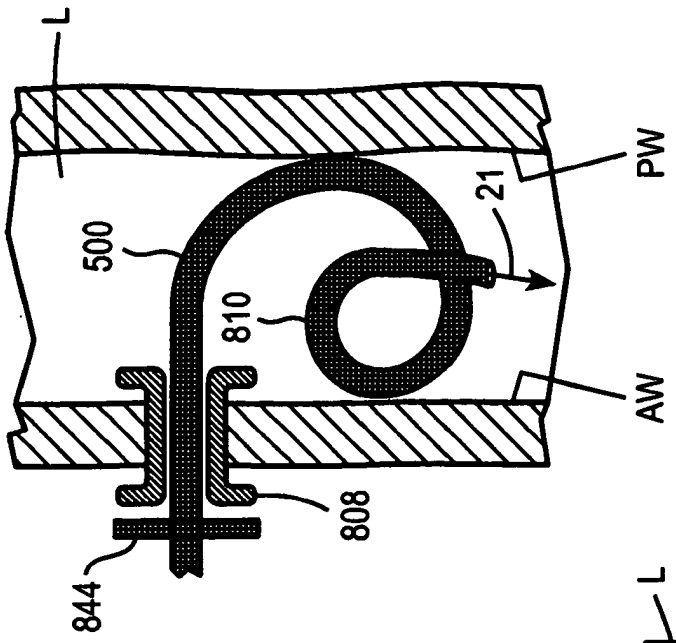


FIG. 25

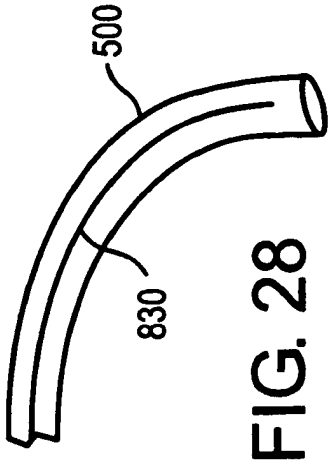


FIG. 28

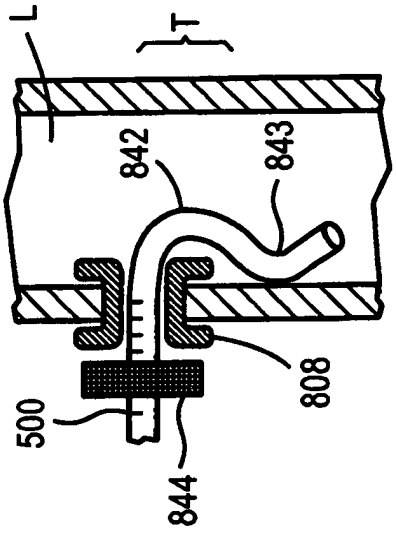


FIG. 27

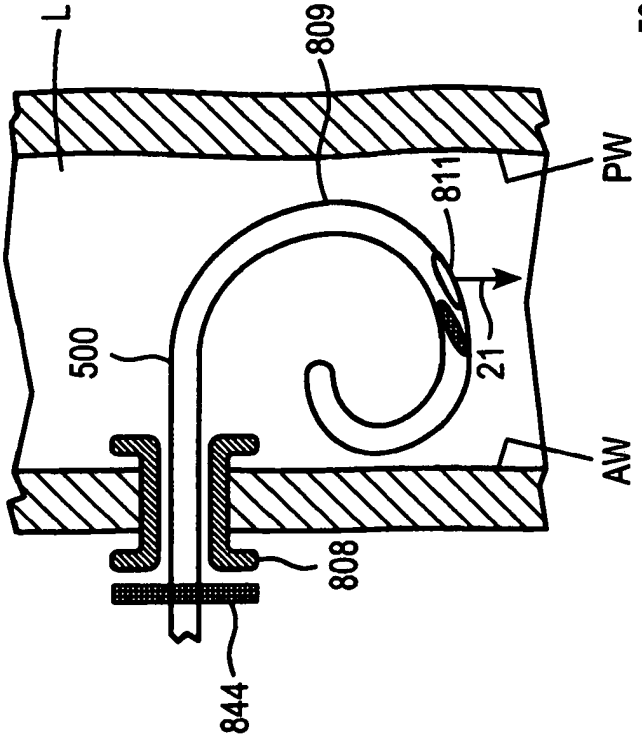


FIG. 24

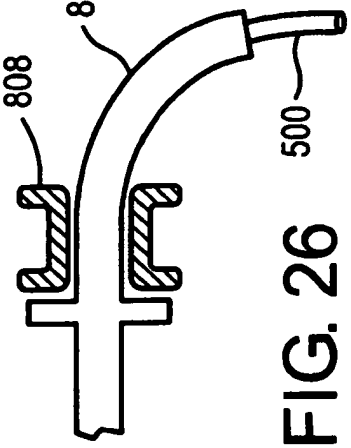


FIG. 26

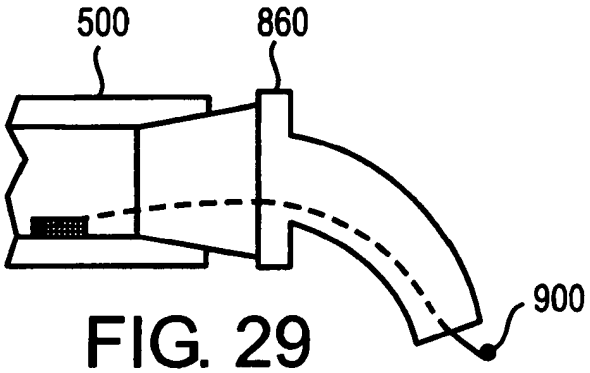


FIG. 29

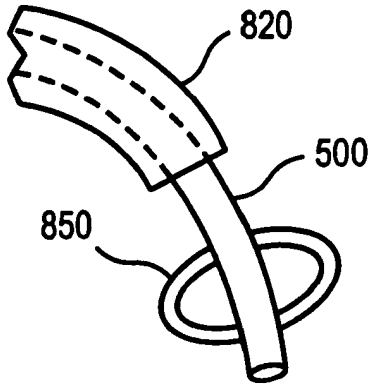


FIG. 30

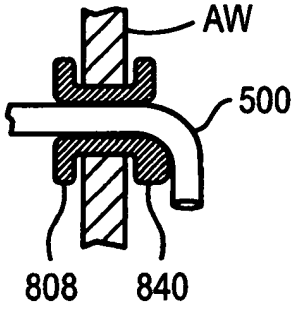


FIG. 31

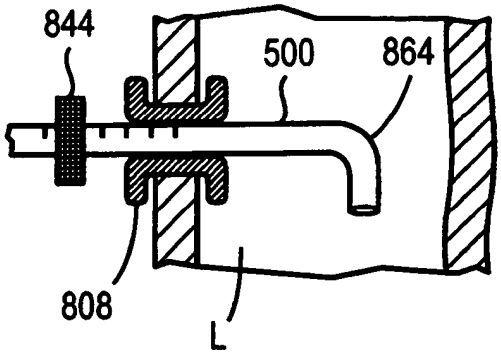


FIG. 32

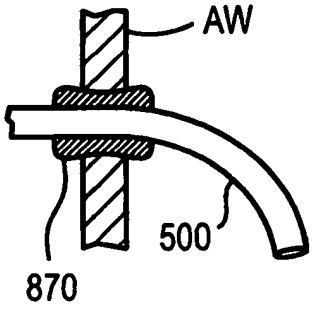


FIG. 33

FIG. 34

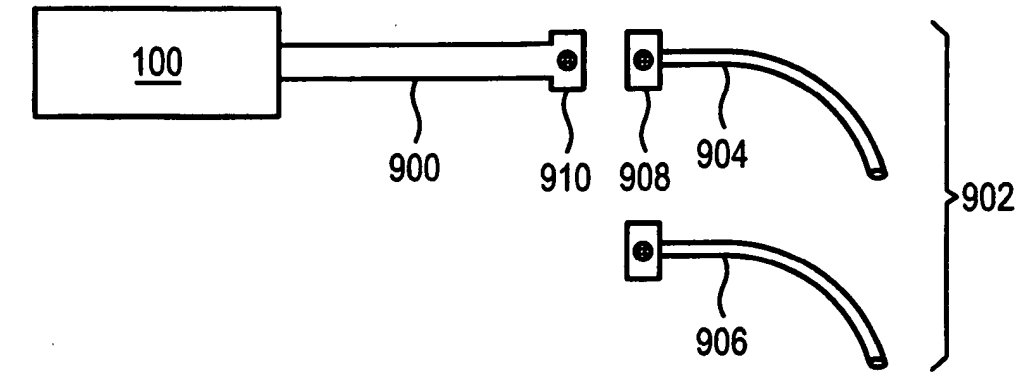
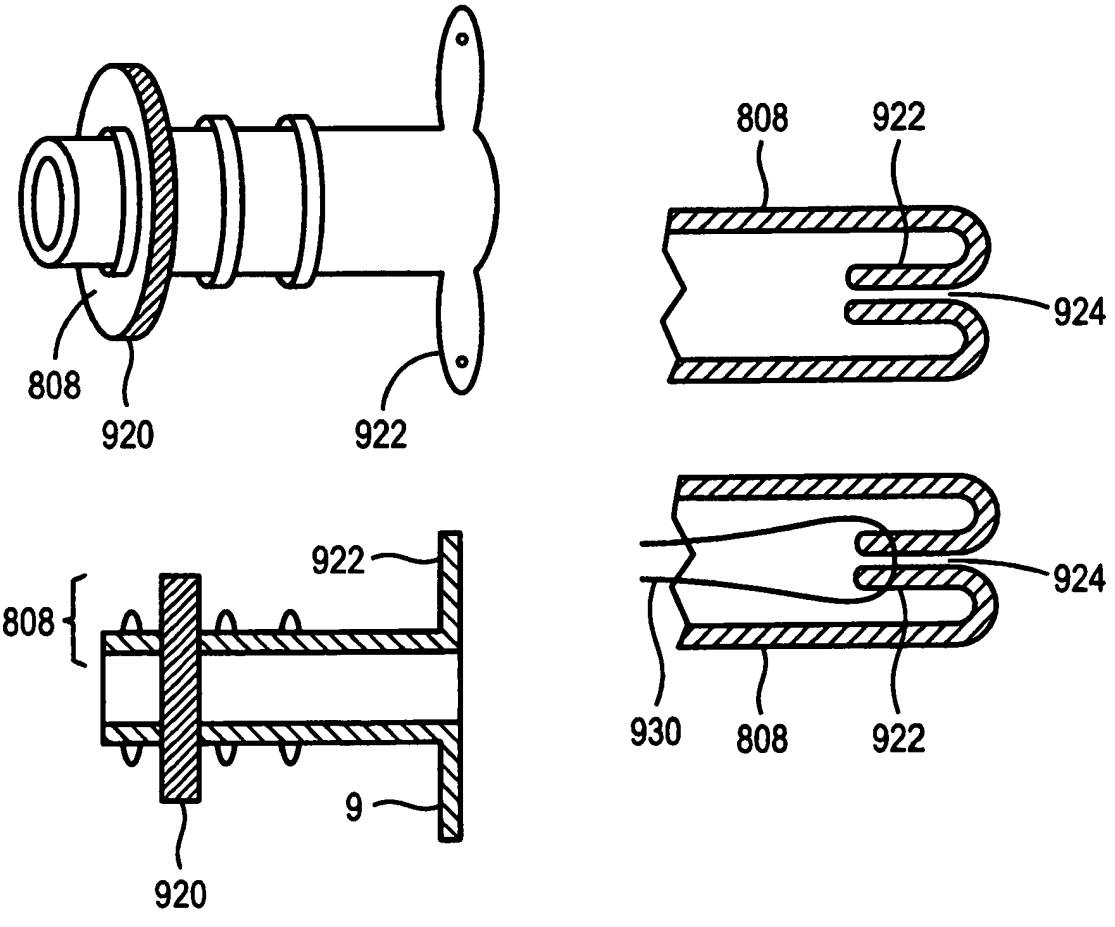

100
900
910
908
904
902
906

FIG. 35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922
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920
924
930
808
922

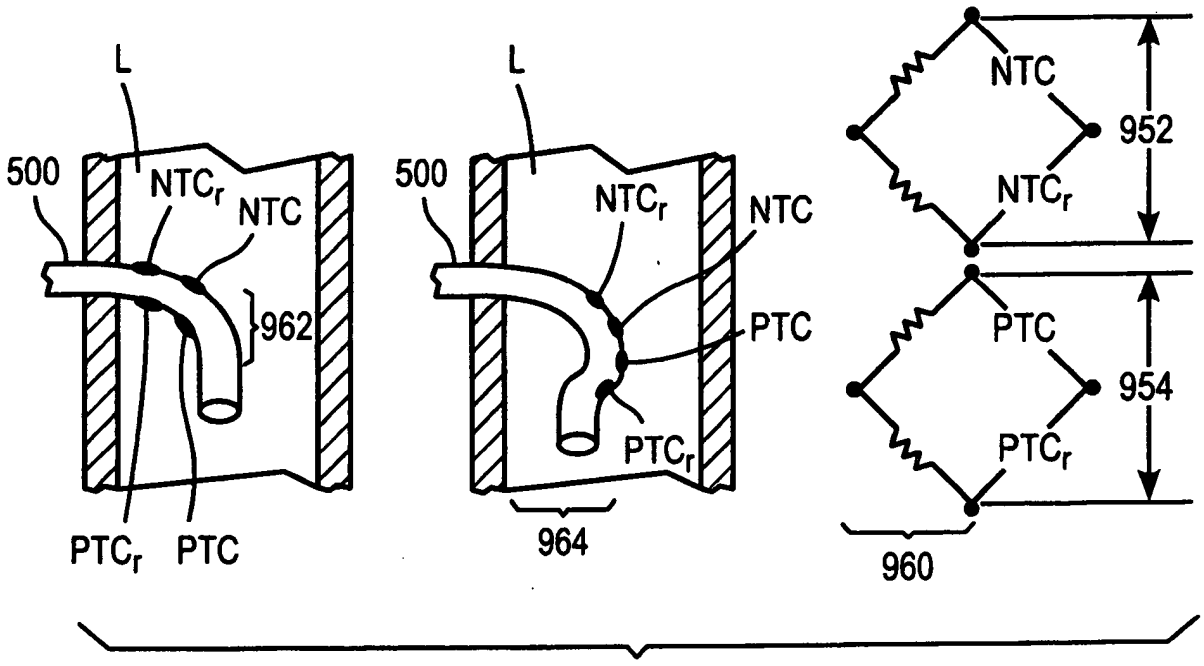
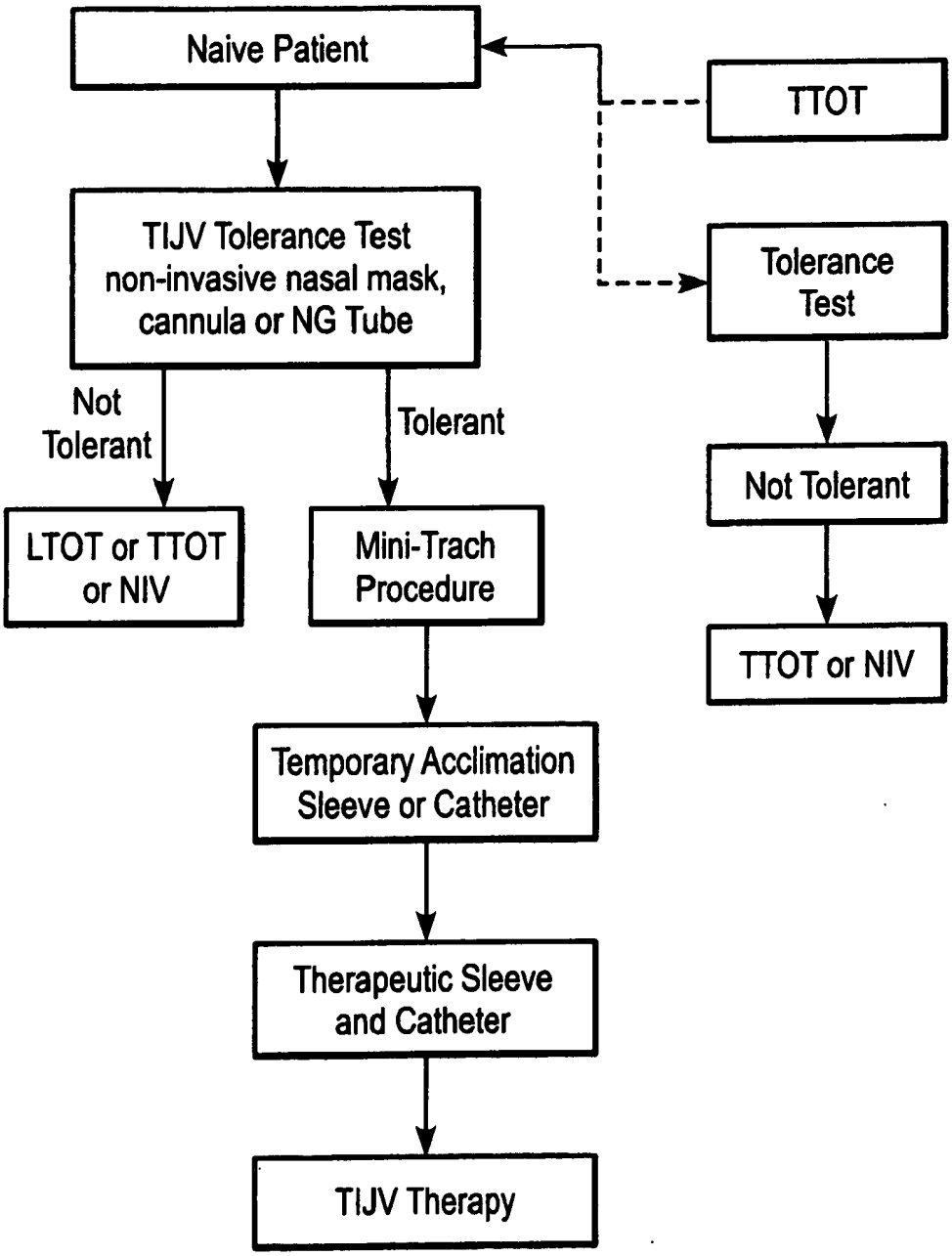

L
500
NTCr
NTC
962
PTCr
PTC
L
500
NTCr
NTC
PTC
PTCr
964
NTC
952
NTCr
PTC
954
PTCr
960

FIG. 36

FIG. 37


Naive Patient
TTOT
TIJV Tolerance Test non-invasive nasal mask, cannula or NG Tube
Tolerance Test
Not Tolerant
Tolerant
Not Tolerant
LTOT or TTOT or NIV
Mini-Trach Procedure
TTOT or NIV
Temporary Acclimation Sleeve or Catheter
Therapeutic Sleeve and Catheter
TIJV Therapy

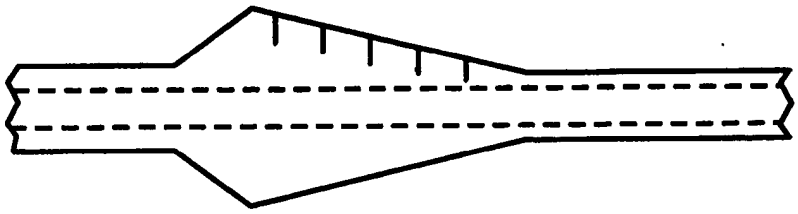


FIG. 38

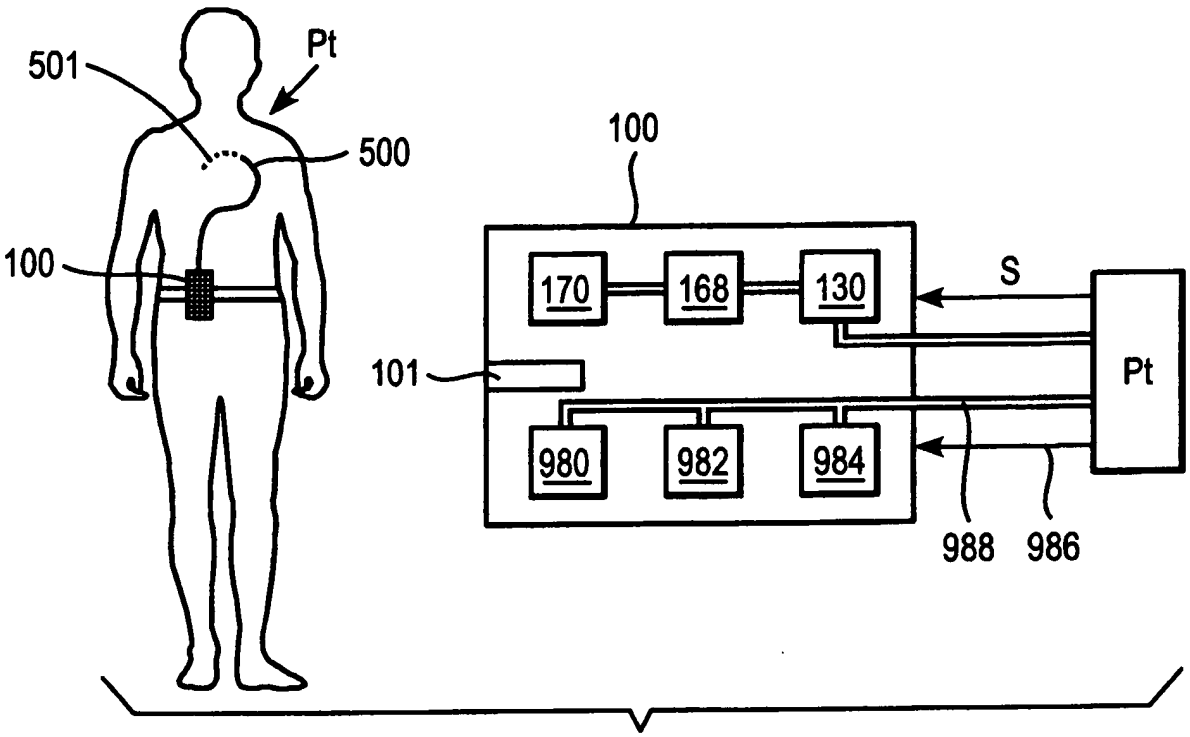


FIG. 39